THE MEDICINES SCENARIO IN INDIA :

PERCEPTIONS AND PERSPECTIVES

Delhi Society for
Promotion of Rational Use of Drugs

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Edited by:
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Foreword

The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) has, with the support of the India-WHO Programme in Essential Drugs, been initiating and implementing programmes in rational use of drugs since 1994. The model comprehensive programme, which has been developed in Delhi State, has now been extended to other states in India. The Society works directly with state governments and, in some states, with non-governmental organizations. The experience gained by us is valuable and has enabled the experts in our programme to objectively assess the present scenario in the field of medicines in this country. More so, it has led us to identify clear cut areas where change or strengthened activity is necessary if we are to provide good quality medicines to the people of India at prices they could afford.

The Society feels that the experience gained and the suggestions for change should be widely disseminated at this very important turning point in the field of medicines. That is why this book is being published.

There are several reasons why this appears to be the appropriate time for this publication. The Government of India will soon be coming out with a new Drug Policy for the country. There are too many drugs circulating in the country and one cannot be certain that all drugs are of the requisite quality. New treatment options and technical innovation in the manufacture of new drugs and vaccines are being developed. The Drugs and Cosmetics Act enacted in 1940 with all its amendments is unable to cope with the situation today. The entry of multinationals in the country, the World Trade Organization and the advent of TRIPS from 2005 have created a need for development and implementation of new systems.

The authors of the nine papers were requested to be positive and yet be critical because unless we know our weaknesses and constraints, we will not be able to overcome these. They have responded to this request and the recommendations contain twenty-two major areas where change in systems or strengthening of the existing system is urgently needed.

We hope that this publication will be useful not only at this time but also in the future and that the suggestions and recommendations made will be discussed by all those who are interested in ensuring that the people of India, and particularly the poor and needy will always have access to essential drugs.

Prof. Ranjit Roy Chaudhury
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DRUGS REGULATION IN INDIA - A CRITICAL REVIEW

P. Das Gupta

The Drugs Act, enacted in 1940, aimed to meet essentially the requirements of the time. Drugs were mostly imported and the few manufacturers in India mostly produced sera and some vaccines, therapeutic tinctures and spirits. Emphasis at that time was on quality of drugs, as was the practice in the countries having a Drugs Act.

The Drugs Act vested the Central Government with powers to control the import of drugs, and the states with the rest of the regulatory activities viz. control over manufacture, distribution, and sale of drugs. As there was no export of drugs the Act was silent on that aspect.

Despite several amendments made in the Drugs & Cosmetics Act (the Act) over the years, the Act is found to be inadequate to meet many areas of contemporary concerns. For example there are no provisions relating to control on exports. The Act is also silent on safety, efficacy and rationality aspects of drug evaluation. Efforts continue to meet some of the deficiencies through the Drugs & Cosmetics Rules (the Rules), which in a way, are more elaborate than the Act. Yet, rules without enabling provisions in the Act are like paper tigers which cannot stand scrutiny when challenged in a court of law.

In the USA and in Europe the drug regulations were drastically changed after the thalidomide disaster in the sixties, when the existing Drugs Acts were amended or new acts introduced (e.g., Medicines Act, 1968 of the UK, Kefauver Harris amendments, 1962 in the USA). In India there have been no such compulsions as it had not to face the thalidomide disaster, like other countries.

The abundance of new drugs, new treatment options, technological innovations in the manufacture of new drugs and vaccines, the Indian Patent Act of 1970, the entry of multinationals in a big way in the pharmaceutical sector, the World Trade Organization agreement and the looming provisions of TRIPS have all changed the scenario from 1940 when the Drugs Act was framed to meet the need of those times. The emphasis at that time was only on the quality of drugs. The provisions of the Act need to be looked at carefully and a fresh set of amendments, or indeed, a new Drugs Act needs to be framed to

ensure safety, efficacy, rationality and quality of drugs. The new Act would ensure that rational formulation of drugs would be enhanced. It will also encourage the development of new drugs from molecules discovered in India.

There are no definitions of 'generic drug', 'bulk drug', 'new drug', and 'patented drug' under the Act. In the absence of specific drug rules for the grant of license to manufacture bulk drugs, no technical expertise has been developed at the state level for examination of the manufacture of the same. The definition of 'new drug' that is provided in the Rules should be brought into the Act. Further, the explanation of 'Patent and Proprietary Medicine' as given in the 2nd schedule of the D&C Act is a misnomer under the Patent Act, and also because a simple disclosure of the contents on the label does not satisfy the requirements of efficacy, quality, rationality and safety of a drug formulation.

The power, functions, qualifications and experience of the licensing authorities or of senior officers responsible for administration and enforcement of activities under the Act, both at central and state levels should be provided in the Act, which currently deals with scope and functions of only the Drugs Inspector and the government analyst - two junior level officers. This has led to some anomalies.

Some of the states have the Director of Health Services and others have officers of the Indian Administrative Services and the Indian Police Services to head the Drug Control Organization. This is possible as the head of the organization has not been identified with the licensing or controlling authority whose qualifications and experiences are in the Rules.

Since the powers have not been discussed such officers function with perceived notions to oversee and supervise the activities of the juniors. This deficiency should be rectified as some of the Acts introduced in the recent years provide for the qualifications, power and scope of the Head of the organizations as for example in the Trade Mark Act, 1999. In developed countries, the Act itself prescribes the attributes of the Head of the organization.

There is no provision in the Act for Central Licensing. Some efforts were made to introduce the concept of Central Licensing Approval Authority through the Rules to regulate blood banks and the manufacture of LVPs, Sera vaccines. It is necessary to have a uniform licensing policy and machinery to control the manufacture of sensitive and high technology drugs.

The state of the art of screening formulations and the policy to allow or disallow manufacture of a formulation is not uniform amongst the

states, and there is no bar for a drug licensed in one state to be sold in the whole of India. In order to bring in uniformity, it has been agreed, in the Drug Policy 1994, that inter-state commerce in drugs would be regulated. This is proposed to be achieved through a system of registration of drugs by the Centre before they are allowed to be manufactured under state licensing. The proposal for central registration should not cause conflict between the states and the centre as the licensing power of the states will remain unaffected and valid within the limits of the state.

The parameters of safety and efficacy of a new drug formulation are included in Schedule Y of the Rules only. There is thus, no legal scope for the licensing authority to prevent the manufacture of a formulation containing old drugs even if it has not been screened for safety, efficacy and rationality as the Rules apply to the new drugs only. The Central Government has powers under Sec. 26A of the Act to ban a drug on the grounds of inadequate safety, efficacy and rationality, after the drug is marketed. Thus, unless a marketed drug is noticed by the Central Government as likely to be violative of Sec. 26A, no action is initiated. It is a vicious cycle of allowing the licensee to manufacture a formulation by the state and then banning it after an elaborate procedure to examine it's safety and rationality. This results in wastage of time and money in investment and sale of the offending formulation. The system of registration proposed above may be made adequate by including the provision of evaluation for safety and efficacy of medicines.

The Drugs Consultative Committee (DCC) under section 7 is a purely advisory committee "on any matter tending to secure uniformity throughout India in administration of the Act". The DCC consists of one representative of each state and two representatives of the Centre. It advises both the central and state governments. Unfortunately, this Committee has no teeth and its recommendations may be accepted or rejected by the central or state governments. Consideration should be given to making mandatory on the governments, the advice given by the DCC just as is the case with the recommendations of the DTAB.

The Drugs Act does not include medical devices except for a few notified contraceptives and sterilised syringes and needles. There should be a separate chapter for regulation of medical devices, which should regulate the import, manufacture and sale of, amongst others, the pacemakers, orthopaedic prosthetics, intraocular lenses and life-support systems.

The country is entering into a global patent regime. While a new Patent Act is being introduced in the country, the Drugs Act also requires to have certain provisions for a patented drug and for patent violation.

In developed countries, the Drugs Act prescribes a time frame for a generic application filing. For example, in the US an application can be submitted and processed during the pendency of a patent, and the applicant is permitted to manufacture the drug effective from the date of expiry of the patent. This is not permitted in the UK, where the application can be submitted only after the patent expires.

Further the patent life may be extended upto 3 years in the USA for delay caused in the process of registration, and for a period of six months after completion of a successful pediatric trial. Protection is also given to the first applicant of a generic drug for a period of four years depending upon the amount of data the subsequent applicant generates. To obtain the same treatment as the first applicant the subsequent applicant has to generate the same amount of data. Before a generic approval is given after four years it is compulsory for an applicant to conduct bioavailability studies. In India generic approval is given by the Centre up to four years from its introduction as a 'new drug'. No such study is required after this period and a licence to manufacture can be obtained from the states.

The drug laws of the developed countries are seriously tested with two new developments: use of information technology (IT), and parallel imports. IT is being utilised for dissemination of drug information directed to doctors as well as consumers through websites, and e-commerce for ordering and supply of drugs directly from the consumer to the manufacturer and vice versa, without prescription. While UK has prohibited e-commerce in drugs, this is permissible in the United States of America.

The Drugs Controller General is responsible for allowing new drugs, developed either in India or abroad, to be clinically evaluated in the country before release which is also the responsibility of the same office. At the present time, the Indian Council of Medical Research provides advice to the office of the Drugs Controller General regarding clinical evaluation of the new drugs. Sometimes, the Drugs Controller General sends new drugs for evaluation to experts without asking for the advice of the ICMR. Sometimes a special committee is formed to evaluate a particular drug. The office of the Drugs Controller General has the prerogative to use any of these mechanisms. However, in due course, it would be appropriate if the office of the Drugs Controller General becomes a National Drug Authority with its own laboratories at New Delhi and in the regions as already planned, with its own expert groups, specialized committees and task forces, its own complement of chemists, pharmacists, biochemists, toxicologists, pharmacologists, microbiologists, clinical pharmacologists and clinicians. The method for assessing, reviewing and clearing new drugs should

become uniform, transparent and rapid so that Indian pharmaceutical researchers could get their new drugs assessed and cleared at the earliest so that they could compete with other international pharmaceuticals with advantage.

It may be noted that in the USA, parallel trading in drugs was permitted under a law enacted in 2000 and signed by President Clinton. This Act has, however, been since repealed after FDA submitted a detailed report explaining the difficulty in quality control as the US law requires the importer to have its own testing facility and to get each batch tested before certifying it fit to be sold. The creation of two separate testing facilities for the same branded product is repugnant to law.

It is necessary that while drafting amendments to the existing Act, these issues are also considered and a nationally acceptable position is taken.

The offences under the Act, need to be reviewed. It is necessary to provide for compounding of offences with powers given to the licensing authorities to impose fines. The provision of show cause notice to the licensees requires amendments to deal with cases of spurious drugs, accidents in the work place, and death resulting from adulterated drugs due to violation of GMP so as to enable licensing authorities to seize the manufacturing premises or other licensed establishments to prevent loss of valuable evidence. While the licensing authority shall retain the power to prosecute offenders for offences leading to imprisonment with fine, other offences shall be disposed of in 'hearings'. The Drug Policy of 1994 has provided for hearing and this option should be available to the aggrieved party. If this procedure is established, confiscation of the offending material may be made by the drug inspector without a court order. In such cases an appeal against the order given in a hearing may be made directly to the High Court. Cases filed by the Government for offences under the Act shall also be in a High Court for expeditious justice.

The drug prices are not covered by the drug regulations in this country, but are controlled through an administrative order issued under the Essential Commodities Act, by the Department of Chemicals & Petrochemicals, Ministry of Chemicals & Fertilizers. The state drug controllers are made responsible for implementation of the order and deal with the offences under the order. With the state drug control machinery hardly adequate, the implementation is tardy with no action possible in most parts of the country because there are few drug inspectors.

It has been observed that price control, wherever existing, is not under the drug control regulations, and in most countries is a negotiated

settlement between the Ministry of Health and the manufacturer. If this model is not workable due to the large number of manufacturers in the country, it may be possible to involve NGOs as nodal agencies to enforce price control orders. NGOs may be empowered to initiate legal action through the public prosecution agencies. It is not feasible to adequately enforce price control through the drug control organization of the states.

The principal problem of the drug control organizations both at the Centre and the states is inadequate enforcement for lack of appropriate machinery due to limited budget provisions. The organization is only a part of the Directorate of Health Services and is not given importance in terms of budget allocations.

There are a total of 1047 drug inspectors in position in the states against the need for a minimum of 2250, and 32 drug inspectors at the centre as against the need for 300; the testing capacity for the Government laboratories is approximately 30,000 samples per year as against the need for testing 150,000 drug samples per year (figures based on a proposal worked out by the Central Government in 1997 for funding under a World Bank Capacity Building Project, which did not materialize).

The concept of a National Drugs Agency was first mooted by the Hathi Committee in 1975. The National Drug Policy announced in 1994 stated clearly that a National Drugs Authority (NDA) would be established. This would deal with issues such as quality control of drugs and rational use of drugs. The Ministry of Health and Family Welfare was to establish the NDA. The same Policy Statement announced also the setting up a National Pharmaceutical Pricing Authority (NPPA) under the Ministry of Chemicals and Fertilizers. While the NPPA became a reality in 1997, the NDA has yet to be set up. No reasons have been given as to why this has not been set up.

Such authorities are viable with substantial income generated by charging fees from the manufactures and dealers of drugs. Central registration and fees chargeable for the same would cover the additional costs for the functioning of the authorities. This process (of increasing the fees) has already been initiated at the state level with success, and can be extended to the national level.

The recruitment rules for the officers of Drug Control Organizations provide straight jacket qualification and experience. This needs to be reviewed, as a flexible approach will ensure motivation and incentive to take on new responsibilities.

PROCUREMENT AND DISTRIBUTION OF DRUGS

R. Parameswar

Procurement and distribution of drugs are two core activities in the overall management of drug supply. Drugs are costly and in public health budgets, next to staff costs, expenditure on drugs constitutes the largest percentage. It becomes therefore important that such resources that are available are utilised optimally. Since availability of resources for financing drugs is always a constraint in India, it becomes all the more important to improve efficiency in all aspects of drug management in the country.

Traditionally, drugs have been provided, free of charge in all public health facilities in India. Unfortunately, over the years, this has not been found to be sustainable, and, as a consequence, the policy of free drug supply has lead to chronic shortages of drugs in public health facilities and a decline in the quality of public health care.

Managing Drug Supply is organised around four basic functions - selection, procurement, distribution and use. Procurement of drugs includes quantifying drug requirements after a selection of drugs, deciding on procurement methods, managing tenders, establishing contract terms and ensuring drug quality and adherence to contract terms. Distribution includes delivery to drug depots and health facilities, stock control and stores management. An effective procurement process should ensure that the required drugs are procured in the right quantities and at the lowest possible purchase price and, further, that the drugs are of quality and that shortages and stock outs are avoided. The real cost of drugs in the public health sector is not restricted to the unit cost of acquisition alone. Unfortunately, the case is that these costs are seldom taken into account by procurement authorities. Many costs are "hidden" such as those arising from faulty distribution, procurement of drugs not required, procurement in excess quantities. The cost of procurement of drugs is also influenced by the efficiency of the procurement organisation. If, for example, tenderers know that payment would be made on time the prices would be competitive if on the other hand suppliers apprehend delays in payment, the cost of delay would be built into the price. In brief, the following factors have a bearing (the list is by no means exhaustive) on the cost of drugs over and above the prices:

- faulty selection list of drugs;
- precise determination of quantity to be procured (over estimation could lead to higher inventory and consequential interest cost, while underestimating the requirements could lead to stock outs leading to local purchase;
- delay in the finalization of rate contracts;
- faulty distribution system which could lead to excesses and shortages within the system;
- poor inventory management; and
- poor quality of drugs (a producer not adhering to GMP might offer more competitive prices as compared to a supplier following GMP standards).

That the above are not mere theoretical postulations, but relate to ground realities in the country have been brought out by a committee appointed by the Government of Karnataka which examined purchase procedures of distribution of drugs and pharmaceuticals in that state. The committee has identified the following deficiencies in the state:

- failure to finalise list of drugs, tenders and finalisation of rate contracts on time.
- improper quantification for tender due to non-receipt of information from institutions.
- tendering work is being attended to by the Directorate of Health which does not have enough time to be devoted to this action.
- rate contract is delayed leading to consequent delay in procurement and supply.
- purchase by the medical stores depot is always delayed due to non-receipt of requirement from indenting institutions.
- all required drugs are not covered under rate contract.
- delay in the release of budget to district surgeons and other institutions.

A sustainable drug supply programme, which in effect means a continuity in the policy aims and objectives over a period, requires financial sustainability, effective organisation and management and, overall, a political commitment. As discussed earlier, one way of ensuring financial sustainability is to improve the efficiency of use of available resources.

There is not enough recognition of the fact that dysfunctional organisations and systems are leading even to the scarce resources being frittered away.

Since it has been found that a vast majority of diseases can be treated with a small, carefully drawn out list of drugs, the starting point of the exercise is to draw up an Essential Drugs List, and identify the drugs for different levels of health care. The second step is to promote rational prescription and dispensing. By reducing the number of drugs and following rational prescription, it is possible to reduce expenditure on non-essential drugs and earmark more funds for essential and vital drugs. This is to be followed by efficiency in procurement and distribution. Integral to the whole exercise is a careful monitoring of drug prescription, prevention of irrational use, patient compliance, drug procurement being confined to generic drugs, timeliness of tender process and completion, execution, delivery, payment to suppliers, quality, storage and inventory control.

Organising drug supply for public health facilities is a major challenge. The following methods exist in India for procuring drugs for public health facilities:

- Central Rate Contract system.
- pooled procurement either by Government direct or through an autonomous corporation.
- de-centralized procurement.
- local purchase.

The general procedure for procurement of drugs, for public health facilities is through open tender. Competitive bids are invited from qualified manufacturers to supply the required quantities.

The tenders may provide for certain minimum requirements to be fulfilled by indenting bidders. These may include:

- bids being only from manufacturers.
- the manufacturers having a minimum level of turnover.
- the drugs being licensed by a competent licensing authority.
- the drugs being in manufacture for a period of time.
- the drugs not having been recalled because of quality defects.

The above list is by no means exhaustive. Each state in India follows its own criteria in use though requirement such as tax clearances are compulsory and uniform throughout the country.

Lately, many states have switched over or are in the process of switching over to a two-envelope system. The merit in the two-envelope system, innovatively introduced in Delhi, for the first time, is that the price bids of only the pre-qualified tenderers need be considered. Under the earlier system, too often one had to make arguments against the lowest tender, which opens up the door for suspicion and charges of subjectivity. In the two-envelope system, transparency is accomplished in that the criteria are known before hand to the prospective bidders. One other means for securing demonstrative transparency and objectivity is to have an independent purchase committee, comprising some non-officials of known integrity.

By and large states follow the open tender system but many states have a policy of price and purchase preference in favour of their state owned pharmaceutical enterprises or in favour of small scale units in the state. Such preferences are uneconomical apart from their inadvisability on quality considerations.

The arrangements exist for procurement are given in Table 1.

A central agency in the state invites tenders for supply of a list of drugs - either giving an approximate quantity of requirements or without indicating the quantity required. After the tenders are opened, in the presence of the bidders, a comparative statement is drawn and placed before a Purchase Committee. After suppliers and prices are decided upon, rate contracts are finalised. The contracts provide as to who may indent for supply. Normally the contracts provide for delivery free of charge to the demanding offices. Based on the contracts so finalised, District Medical Officers/District Health Officers/Superintendents of Hospitals place indents on the suppliers.

A central agency, not only finalises the rate contract as mentioned above, but also arranges for the procurement after ascertaining the quantity required. Usually the contracts provide for direct delivery to the facilities concerned.

District Medical Officers/Health Officers and others invite tenders for their own requirements including those of medical health facilities under them. Under the system, the quantities required are smaller and consequently, the response to tender is generally not adequate and in any case lower than the number responding to a state level tender.

The demerits of this system is that the tender process is replicated in each district, leading to wasteful expenditure. The pressures at a district level on the purchase organisation are also likely to be more than on a state level organisation. The other major disadvantage is the resultant wide variations in the standards of evaluation and in prices from district to district in the state.

Comparative methods/arrangements for procurement and distribution of drugs - merits/drawbacks. Table-1

Model	Response to Tender	Monitoring of supplies	Distribution	Quality		Prices	Merits	Drawbacks
				GMP	Sample tests			
Centralised Rate Contract Suppliers are established with price for each item of drug. Indents are placed by consuming facilities and drugs are directly delivered.	Generally good	Not possible since indents are placed by demanding offices directly.	No problems since these are delivered direct to the demanding officers.	Possible		Competitive	Pre-qualification possible. Quality through GMP possible. Uniform criteria in selection of suppliers.	Suppliers may not quote the best prices because of uncertainity about quantity requirements. No central monitoring of supply possible. No feed back mechanism for exchange of information etc.
Central Rate Contract with pooled procurement	Good	Centrally possible		Possible	Testing of samples possible	Most competitive	Maximum price advantage as bulk procurement yields most competitive prices. Uniform selection. Selective GMP Quality control selecting and surprise checking of batches. Good feedback information.	Estimation of quantities required can pose problems. Unless monitoring is effective could lead to mal-distribution.
Tenders by individual consumption centres	Restricted response especially from major manu-facturers	Easy	No problem	Value of procurement being limited. GMP may not be economically feasible.	Testing possible		(i) No problems of qualification (ii) Effective monitoring.	Wide variation in the state in (i) Selection of drugs (ii) Prices (iii) Suppliers Competition is limited and there may be no significant price advantage over local purchase. Making individual hospitals to invite tenders is wasteful and expensive. The cost of administration of the scheme would be most uneconomical.
Local Purchase	N.A.	N.A.		No quality control	No samples are drawn	High - generally max. retail price	Can be purchased without any lead time.	Expensive. No assurance as to quality.

This is the most uneconomical method of purchases. Usually this is resorted to in situations of emergency: usually, the quotations are invited from a few retailers and rates fixed on the lowest quote.

In reality, there is a mixture of arrangements in every state. It is not that the entire requirements of a state are met by any single method discussed above.

A brief account of the arrangement for distribution and procurement in different states is given below:

The aim of the Tamil Nadu Policy is to purchase quality drugs at competitive prices so as to make use of the available funds and make drugs available in all government health facilities. As a first step, the Government dispensed with the policy of price purchase price preferences to all classes of suppliers (including small-scale sector, local manufacturers) and adopted a policy of open tender. A system of pre-qualification of tenders based on a set of objective criteria was also introduced. As a first step towards effecting economy and bringing in an efficient system of distribution, the Tamil Nadu Medical Services Corporation was set up. The Corporation finalised a list of essential drugs to be procured. The number of drugs was drastically reduced from the earlier 960, recognising that the number generally in use in public hospitals and other facilities is much less. The essential drugs list was prepared by an expert committee which is subjected to periodical review.

In order to streamline distribution a network of warehouses has been established, roughly each district has one warehouse to serve the needs of hospitals and public health facilities in that district. The health facilities take delivery of drugs according to a pre-determined arrangement. Drugs are directly delivered to some of the major hospitals. To exercise budgetary control, each hospital is given a budgetary allocation and a passbook indicating the entitlement and within which it can draw any drug from the district godown.

The Corporation procures 90% of the requirement of the hospitals and other facilities, leaving 10% of the funds to each hospital which can be utilised for purchase of drugs not supplied by the Corporation. The operations have been computerised, each district godown having a computer linked to the central computer at the head office at Chennai. An effective system of quality control has also been introduced. Samples drawn from different batches are coded and sent to private laboratories. The above measures have resulted in improved drug availability in over 2000 medical institutions throughout the State.

The State of Delhi developed a Drug Policy in 1994, as perhaps the first state to do so in India. The aim of the policy is to make drugs available in hospitals and other public health facilities to all patients. In pursuance of the policy, an essential drug list was drawn and a centralised procurement of drugs brought into place replacing the prevailing system of each major institution calling for tenders. As a starting point, the tender procedure was completely overhauled. A set of new tender documents was introduced to facilitate pre-qualification of tenders. Tenderers submit their bids in two envelopes one containing the technical parameters and the second the price bid. The technical criteria specified include a minimum turnover (initially fixed at Rs. 80 million now enhanced to Rs.120 million) adherence to GMP practices. Each drug manufacturer should have a WHO GMP certificate or carry registration for supply to the Indian Army (DGQA) and should have manufactured the drug for a period of 3 years and the tenderer should give a certificate in support of not having been black-listed or his drugs having been recalled for failure. The price tender envelopes of only such of those tenderers whose technical bids are found to be in order opened. A high-level purchase committee with officials and non-officials with the Chairman being a non-official approves tenders.

Initially, a central rate contract system was brought into force identifying suppliers and prices leaving it to the hospitals to place indents. Since 2000, about 90 drugs and formulations, which constitute about 80% of the budgetary outlay, is being procured through pooled procurement. In respect of the remaining drugs the hospitals place orders on the suppliers on whom rate contracts have been finalised at the prices given in the respective contracts.

To ensure quality, the manufacturing premises of a number of suppliers were independently subjected to GMP inspection. Besides this, samples are being regularly drawn from suppliers for being tested at accredited laboratories. The Institutions send the samples to the Directorate of Health Services which in turn sends the samples to designated laboratories.

The measures taken by the Delhi Government have resulted in a substantial reduction in prices as compared to the prices at which drugs were procured earlier. A trend analysis of prices of drugs purchased since the new system was brought into force has brought out that drug prices have been held. The introduction of pooled procurement since 1998 has, in fact, brought down the prices sharply of some of the drugs.

The policy for purchase of drugs for government hospitals, medical institutions in the state of Rajasthan is covered by a policy issued in March 1988. The policy provides that:

(i) ail drugs that are manufactured by public sector units be purchased from them (and if Rajasthan drugs and Pharmaceuticals (RDPL) agrees to supply these drugs at rates lower than or equal to the lowest rates offered by the public sector units, such drugs can be purchased through RDPL).

(ii) drugs manufactured RDPL and not manufactured by other public sector units, be purchased from RDPL.

(iii) all other drugs (not manufactured by any public sector units) may be purchased on the basis of rate contract.

Further, there is a system of reservation in favour of the Rajasthan Small Sector Units. 80% of the orders has to be given to the small sector units of Rajasthan if:

(i) they are able to match the prices; and

(ii) if the quality of the small scale sector is satisfactory.

Tenders are floated for supply of items for which RDPL and other public sector units are not in a position to supply. The procurement is based on a list of 70 basic drugs. Procurement based on the new Essential Drug List is yet to come into force. What is left to be procured in the open is only the residual quantity left over after –

a) supply by RDPL.

b) other public sector units; and

c) by small scale units of Rajasthan (reservation is exclusive only for SSI units registered in Rajasthan).

The Directorate of Medical Health Services has direct responsibility for procurement of drugs for supply to all the district hospitals/and other public health facilities. While it does not have responsibility for supply of drugs to medical colleges, the rate contract finalised by the directorate is operated upon by these institutions.

There is no system of drawing drug samples from individual batches supplied to hospitals as a precondition for making payment. The Drugs Controller of the state draws samples in the ordinary course of enforcement of rules and regulations. Not many samples are collected in this fashion.

In Madhya Pradesh, public procurement of drugs is carried out through a state enterprise Madhya Pradesh Laghu Udyogam Limited (LUN) which procures not only drugs and medical supplies but also other requirements of the state government. Tenders are invited by LUN but preferentially

orders are placed on SSI units in the state. Only if the SSI units in the state are unable to supply, orders are placed on outside suppliers.

The Madhya Pradesh Laghu Udyogam Limited invites tenders based on the state-approved specifications for drugs. The tenders are evaluated according to prices and a technical evaluation, undertaken by in-house expertise. The prices are compared with the cost estimate prepared by LUN prior to the issue of tenders. A marketing committee with a representative from the Directorate of Public Health & Family Welfare, Directorate of Medical Education, etc. is responsible for approving the rates for all drugs listed in the tender. The Committee is authorized to overrule evaluation made by LUN if the quality is sub-standard. Once the prices are approved all qualifying units are invited to sign a rate contract for a period of one or two years.

Hospitals and other public health facilities make direct indents on LUN approved suppliers and only if these suppliers are unable to supply or the drug is not in the rate contract list of LUN, local purchase from private sector is allowed. The rate contract provides for delivery to the facilities. Only 30% of the requirement of drugs is met through LUN.

Procurement and distribution arrangement of drugs in Karnataka are somewhat complicated because of decentralization of powers to local self-governing bodies (Zilla Parishads). Of the earmarked funds for procurement of drugs in the state budget, 40% is operated at the level of the Directorate of Health Services and the remaining 60% is released to Zilla Parishads.

A list of drugs for inviting tenders is approved by the State Government. A two-envelope system is followed. The comparative statement is placed before a Therapeutic Committee which makes recommendations to a High Power Committee and the latter decides on suppliers, drug-wise, with whom rate contracts are entered into. In respect of antibiotics purchases are made directly from the Karnataka Antibiotics Corporation without inviting tenders.

After the rate contracts are entered into, the institutions have to place indents on the Government Medical Stores. Since such indents are not received in time, the GMS processes supply orders on the basis of previous year's supplies. The suppliers supply the drugs to the districts.

In so far as Zilla Parishads and other institutions (with 100 beds or more coming under the jurisdiction of the Directorate of Public Health) to whom 60% of the funds are allocated, they either operate on the rate contracts finalised by the State Government or place orders on public sector enterprises and if unable to procure them in this manner they invite tenders.

Quality control is exercised by the Drug Controller by taking samples from the medicines in stock in the Government Medical Stores. The number of samples tested has been grossly inadequate.

The drawbacks in the existing arrangements of procurement and distribution of drugs in Karnataka have been discussed earlier in this article.

The nodal agency for purchase of drugs in Andhra Pradesh is the drug Procurement Wing of the Andhra Pradesh Infrastructure State Development Corporation (APISDC).

Rate contracts are finalised after inviting tenders, on a selected list of drugs. Indents are collected from hospitals and consolidated by the nodal agency and orders are placed by the firm direct to the medical stores in each district. A pass book system has also been introduced and generally institutions draw drugs on a quarterly basis. Eighty percent of the funds for drugs given to hospitals is procured through central procurement and the balance 20% is utilised for emergency purchases etc.

Drug samples are drawn from district drug stores and sent to recognized laboratories for testing. There is no information available on prices.

Depicted in Table 2 is a summary of the methods and procedures followed in the procurement and distribution of drugs in the states discussed above together with a brief assessment of the methods.

While there is increasing awareness of the rational use of drugs, not enough has been done to improve procurement and distribution procedures. Despite clear success stories, many states have been reluctant to bring about reforms in drug management policies. If an appropriate selection of drugs is made, the chances of drugs being left out of tender, forcing health facilities to make local purchase, should not arise. Both administrators and prescribers have failed to recognize that therapeutic efficiency can be improved through better selection and improving operational efficiently through better organization in procurement and distribution. There are clear advantages in concentrating procurement and logistic efforts on fewer drugs. This would lead to procurement of large quantities when economies of scale of operation would result in competitive prices and procurement of drugs of better quality. In framing a drug policy the primary focus should be on aspects of the health of the people. Consideration of protection to small sector or to state owned public enterprises should be secondary, and such policies should not be detrimental to the health of the people.

Procurement and distribution arrangements of selected drugs with overall assessment **Table-2**

State	Pre-Qualification	Manner of Procurement	Agency	Distribution	Quality Control	Overall Assessment
Tamil Nadu	✔	Pooled procurement	Autonomous corporation	Suppliers asked to deliver direct to district godowns/ major hospitals	GMP not undertaken. Sample testing rigorous	Prices substantially lower as compared to earlier system. Data on trends in prices over the years not available. System has been reported to be effective. Marked improvement in availability of drugs in district hospitals.
Delhi	✔	Pooled drugs constitute about 80% of the value procured. Remaining on rate contract. Hospitals raise indents on approved suppliers and procure the drugs.	Directorate of Public Health	Deliver direct to hospitals In respect of primary health centres, delivery coordinated by Directorate of Health.	Selective independent GMP survyes done. Samples regularly drawn for testing in accredited laboratories	High threshold levels of turnover for pre-qualification (currently Rs.120 million) ensures quality. Independent high level committee with non-officials for finalising tenders ensures objectivity in evaluation. Transparency in procedures. Significant savings in prices as compared to earlier system. Prices under control over the last five years. Marked improvement in the availability of drugs. Independent surveys have found that patients are getting the drugs prescribed.
Madhya Pradesh	×	Centralised Rate Contract. Preference to SSI units in the state.	Laghu Udyogam Nigam (LUN). (Besides drugs, LUN also responsible for remaining items required by Govt.)	District Hospitals/ District Health officers make direct demand on contracts finalised by LUN.	Quality control only as part of the process of drawing samples by the Drug Controller	Only 30% of the drugs required are made by LUN. For the remaining, tenders are invited by district hospitals, etc. There is overall shortage of drugs and medicines in all hospitals forcing patients to buy these from private retail outlets at high prices.

Contd.

Table-2 *(Contd.)*

State	Pre-Qualification	Manner of Procurement	Agency	Distribution	Quality Control	Overall Assessment
Rajasthan	×	Centralised Rate Contract	Directorate of Medical Services	Indents are placed by facilities	Samples are drawn by Drug Controller as part of normal regulatory enforcement.	Reservation in favour of State Drugs & Pharmaceuticals Corporation. Roughly 50 to 55% of the quantities required are purchased from the corporation. Reservation in favour of small scale sector units registered in Rajasthan. What is to be procured in the open is only the residual quantity left over after supply by – RDPL, other public sector units, small scale units of Rajasthan (reservation is exclusive only for SSI units registered in Rajasthan) No data on price available.
Karnataka	✔	Centralised Rate Contract system	Department of Health & Family Welfare	Govt.Medical Store supply 40% of requirement of the institutions other than primary health centres. GMS meets the requirements of primary health units directly. Remaining 60% is released through Zilla Parishads and institu-tions having 100 beds or more working outside the purview of the Zilla Parishads.	Samples are drawn by Drug Controller in the course of his normal work.	Multiple systems of distribution in operation. Delay in timely finalisation of drugs, tenders. Quantification of requirements of drugs not proper. Many drugs are not covered under the rate contract. No uniform procedure in the state. Logistics of distribution poor.
Andhra Pradesh	×	Rate Contract system	Drug Procurement Wing of the APISDC	Indents are collected from various hospitals and consolidated in the Head office and orders placed on firms in rate contract. The drugs are delivered to the district stores of the Central Drug Store.	Drugs are taken at random from the district and sent for analysis to recognised laboratories.	Have the general features of pool procurement. 80% of the budget for drugs required are supplied through the procurement wing of APISDC and 20% retained by hospitals. No assessment is available on working or trends in prices.

STRENGTHS AND WEAKNESSES OF THE PHARMACEUTICAL INDUSTRY - A REVIEW

Prafull D. Sheth

In India, the political, economic, and social outlook remains rather complex. This sector is defined by five critical skills - manufacture, research, development, marketing, and distribution. The world pharmaceutical industry is a research based manufacturing business with an annual growth rate of ten percent. The growth of the Indian industry was estimated to reach fifteen percent annually through the end of the decade. The world market for pharmaceuticals was estimated to be USD 337 billion in 1999. Some 24,000 manufacturers of the Indian pharmaceutical industry produced pharmaceuticals worth about USD 3.0 billion in 1995-96. It was projected that by the year 2000, the production of pharmaceuticals in India will be around USD 4.4 billion or approximately 1% of the global market.

While exports grew at a healthy rate, the 2000 domestic market growth of 11% does not compare well with 13% in 1999, and the need for at least a 14% growth to allow globalisation and expanding R&D investment that does not compromise the need for an ongoing, acceptable earning growth. Ideally, in a partially price controlled, cut-throat market the industry needs at least 15% growth to take bold initiatives, such as establishing a global generic franchise and basic research. This scenario calls for a continuing healthy GDP growth exceeding 6% and ideally around 10% for the Indian economy, something that the industry cannot control.

For drug companies, research and development is the lifeline. Due to a long development timeframe, high odds against success and large resources required both in terms of people and money, pharmaceutical R&D is associated with high risks. For every 10,000 New Chemical Entity (NCE) in discovery, ten enter preclinical development, five enter human trials and one may be approved. Present cost estimates for the entire activity for a single commercial NCE in USA range between USD 400-500 million spread over ten-twelve years. For India, the estimates for the development of new NCE is often quoted to be USD 90-100 million due to lower input cost. On the other hand, for the development

of a Novel Drug Delivery System (NDDS), it may take two to eight years depending on bio-equivalence (BE) or clinical route. The average cost of development would be USD 2-30 million and, chances of viable success are better. The global sales of NDDS were expected to reach USD 31 billion by the turn of the century with an average rate of growth of 15 percent.

Ranbaxy is the only Indian company that has undertaken foundation building strategic initiatives to become a global company. Cipla has a very focussed business approach. With heavy investments in basic research facilities, Wockhardt has developed new anti-infective compounds. Dr. Reddy's Laboratories has shown substantial tangible results in areas including basic research. Amongst all the Indian companies, it has made the most out of its research and development investment. Developing a drug and formulation is only half of the challenge of bringing a molecule to market. An increasing challenge is how to introduce the drug into the body to deliver its therapeutic effect and simultaneously to create a complex assembly line for manufacturing, filling and packaging components at high speed and with high precision. As a by-product of biotechnology driven drug discovery, more and more of the therapeutic agents are peptide in nature. Peptides do not lend themselves to traditional oral routes of administration because they are destroyed in the digestive tract before being delivered to the bloodstream. For this reason, injectable dosage forms are the norm for protein delivery. Indian manufacturers need to make efforts in this direction.

India should be able to meet, by the year 2005, her commitment to product patents. Exclusive marketing rights (or the EMR mechanism) are being implemented and should make some significant Intellectual Property (IP) protection available even sooner. Both houses of parliament have considered the proposed IP legislation though various and shifting political forces continue to force the coalition government to delay the final reading and the vote so as to enable it's final implementation. However, India can ill afford to abrogate the commitments already made, and in any case, more and more of the opposing groups are gradually coming to accept the long term benefits of the GATT agreement. Metamorphosis of the global as well as the Indian pharmaceutical sector – being catalysed by GATT and other factors that are pushing mergers and acquisitions – is bound to completely transform the pharmaceutical industry and distribution systems. Even retailing of medicines will undergo a transition with the entry of multinational retail chains in the country.

There are only four years to go before the product patent bill, and we have only two discovery research projects of Indian original having

moved to phase I/II clinical trials. While this is no different from the path Japan travelled through in the period between 1975-1990, Indian companies will need to do much more, and faster, to gain a fighting chance for a position on global pharma rosters. Not surprisingly, only five Indian companies have undertaken any serious R&D investments, and even these are necessarily meagre, given the limited profitability and the low value of the rupee. Much of the "research" efforts are still focused on analog research, as that is not only financially affordable, but also what the current skills level would allow. While India is very strong in process chemistry, biology and applied biochemistry will require government-academia-private sector initiatives, as well as enormous investments. The start in the short five years or so however, has been quite encouraging, and the outlook is very bright indeed, given the very talented and highly educated workforce and increasingly global resource base of the selected companies. R&D require two distinct sets of skills. Research or discovery skills call for an established infrastructure and a tripartite collaboration between the private sector, academia, and the government – something that comes only from experience of a few decades. It will clearly take India some time to fully establish this, though the "new science" of biotechnology should eliminate many of the impediments along the way.

The New Drug Delivery System and Clinical Development, the 'D' of Research & Development, offers more near term opportunities, due to the availability of large patient populations for many major diseases plus well run hospitals in major cities which can adopt Good Clinical Practices (GCP) standards that meet the US FDA requirements. The Clinical Research Organisation (CRO) activity is ideally suited to India, especially for the more costly Phase II and Phase III trials. In addition, many large selling drugs are going off patent in 2006, opening up a window for filing of New Drug Applications.

Indian pharmaceutical company managements are now experienced and bold enough to accept the inevitable patent battles with innovator companies. Companies have acquired manufacturing facilities in developed countries, and have a prominent presence in many smaller countries to sell branded generics. This is a major shift from the previous years when the focus was on Russia, Africa and such less developed markets. The resulting rapid cashflow growth should accelerate the Indian pharmaceutical companies' global expansion as well as the necessary investments in R&D.

While many negatives plague the Indian pharmaceutical industry, the recent penetration of the rock-bottom low priced "generics generic" has caused the prices and margins to erode for many companies. It is now common to have a dozen brands of a large molecule in about

6 months of its introduction in the western markets. Cut throat competition now faces more damaging competition as "generics generic" is sold to the end consumer at the same price as branded generics, but at the expense of the manufacturer, while wholesalers continue to earn their usual forty percent margin. This is likely to be a transitory consolidation process, where the strong will eventually emerges stronger.

With medicinal plants becoming endangered and several species getting lost, the industry is clamouring for incentives in the form of funds for agrotechnology, soft loans to farmers taking up cultivation of medicinal plants and investments for Green House Development. It is argued that 95 per cent of funds are devoted to other areas and there is need to have a specific percentage of Research and Development. Incentives for Research & Development activities, and more importantly to facilitate clinical trials to validate claims made about most formulations, improving quality and quality control systems are highly recommended.

Major industrialised markets are consuming ninety percent of the pharmaceutical products, while accounting for about 10% of the world's population. India's base is rather low, less than $1 per year per capita being spent on pharmaceuticals. Some of the "tiger countries" are approaching double digit spending but much below the triple digit figures in the west. "New science", driven by the tools of biotechnology, provides a clean slate opportunity for indigenous pharmaceutical companies in many of the emerging countries – lack of any discovery research heritage notwithstanding.

Most countries around the world control drug prices, some more rationally and transparently than others. In India, the National Pharmaceutical Pricing Authority (NPPA) is struggling to find middle ground between need for low cost medicine and industry profits adequate to enable the pharmaceutical industry to carry out discovery research in earnest while also investing in globalisation. This is a difficult task, and the outlook remains confused, and one of the key negatives regarding western pharmaceutical company expansion in India.

The insurance sector, after thirty five years of government monopoly, opened to the private sector 4Q 2000. About six big multinational insurance companies started offering coverage, including health insurance. Until now, medical insurance was not actively sold and few could afford the protection. The anticipated 25% growth per year in medical insurance contracts will open up new segments to society and enable the pharmaceutical companies to offer innovative products as the ability to pay increases.

About a dozen companies are preparing for GMP approvals from inspecting authorities of the industrialised or "regulated" countries, including the US FDA, UK-MCA, Australian TGA, and South Africa MCC. Active pharmaceutical ingredient (API) and dosage form plants of Ranbaxy, Cipla, Wockhardt, Morepen, Cheminor and Neuland are already approved by multiple authorities. Pharmaceutical industry exports from India jumped 27% in 2000, making it one of the fastest growing sectors in India.

Regulation in the pharmaceutical sector is often less consolidated and the interaction between the different states and centre is not always balanced. In addition, the resources that can be made available for the implementation of regulatory work and control are not always adequate for the task that regulatory authorities are expected to undertake. This puts special responsibility and burden on decision makers and regulatory officials, the regulatory over the past decades has been crucial in ensuring that medicines are produced in the country not only for our own population but also for the international market. The fact that cost of medicines in India is one of the lowest in the world has itself been quite redeeming. As new molecules are being introduced in the country at a faster pace, the Indian regulatory agencies have a much larger role to play, by strengthening systems that monitor drug development, approval and life cycle of these molecules. It is imperative that regulatory stays tuned to the emerging scenario and takes appropriate and timely steps to ensure proactive and progressive regulation.

Drug counterfeiting is now one of the fastest growing economic crimes threatening both the developed and the developing world alike. It is estimated that about 15% of all drugs in circulation in the global market are counterfeit and/or substandard. Counterfeiting can apply to both branded and generic products. In the developed countries it does not receive much publicity, but in the developing market, continuous surfacing of counterfeiting products is a matter of serious concern. Experts assume that as many as 7% of world total legitimate pharmaceutical sale already consists of dubious drug products. In India, the actual magnitude of the problem may only be speculated. However, the multifaceted newspaper stories on such incidences puts the whole pharmaceutical fraternity in a poor light and erodes the confidence of the public in the normal distribution channels, industry and drug control organisations.

QUALITY ASSURANCE OF DRUGS

P. R. Pabrai

The main purport of the Drugs and Cosmetics Act, passed in 1940 when we were still under the British rule and when hardly any indigenous pharmaceutical industry existed in the country, is to regulate the import, manufacture, distribution and sale of drugs in the whole of India. The Drugs and Cosmetics Rules were framed under the Act in 1945 to implement the provisions of the new law. The preliminaries to create the machinery to implement the law took some time. So the real efforts towards its implementation began after independence. After the initial euphoria of becoming a free country and attending to the unprecedented problems of rehabilitation of the unimaginable number of evacuees from Pakistan, the country settled down to routine business. Somehow the policies of the 'license-permit Raj' became the order of the day. Drug regulation could not escape its stranglehold. The word 'control' became sacrosanct to such an extend that the officers become controllers rather than regulators, and advisors became controllers. All the heads of departments at the Centre and in the states are designated as 'drugs controllers'. On the other hand, the USA calls its agency the Food and Drug Administration (USFDA). While it enforces the law firmly and does not spare even big multinational companies, if need be, it does not harass them for minor infractions.

The Indian pharmaceutical industry has grown phenomenally after independence. The Indian Patents Act 1970, which did not protect product patents, provided an opportunity to the industry to develop alternate methods of manufacture of existing drugs. In course of time, some of them became world leaders. Presently the industry is meeting, not only practically all the country's needs for medicines, but is also engaged in substantial exports to the developing as well as the developed world. Some of them have developed the Novel Drug Delivery Systems (NDDS) which have been licensed to multinational companies and earning them and the country valuable foreign exchange. We have now reached a stage where quality and not quantity, has to receive prime attention. Some Indian companies have even started investing in new product research as opposed to process research.

With the WTO coming into full operation by 2005 in India and the consequent recognition of product patents, some of the multinationals

are showing interest as eager entrants for introducing their latest drugs in the Indian market. This has opened up new avenues for those who strive for quality. The small-scale sector may find it difficult to withstand the pressures of the opening market. Thus, there is a need for consolidation of the small units and/or undertaking contract manufacture for larger manufacturing units. However, they will have no alternative but to inculcate manufacturing and quality assurance discipline in their operations. They would manufacture fewer items but under excellent manufacturing conditions with the requisite quality management infrastructure.

The quality of drugs used in the country is regulated under the Second Schedule to the Drugs & Cosmetics Act. It essentially provides that the standards of quality specified in the Indian Pharmacopoeia shall apply in respect of drugs included in it. For drugs included in other pharmacopoeia like the USP, BP, Eur. P., etc., standards included in such pharmacopoeias shall apply. For others, the quality standards approved by the licensing authority are applicable.

It is pertinent to point out here that only four editions of the Indian Pharmacopoeia have been published between 1955 and 2000 and a total of 6 Supplements/Addenda to update them. On the other hand, the British Pharmacopoeia and United State Pharmacopoeia come out as a new edition every 5 years with an Addendum annually. The BP now gets revised every year. With the rate at which the pharmaceutical sciences and technology are advancing, it is imperative that the Indian Pharmacopoeia should also create the necessary infrastructure to bring out at least a new edition every fifth year and an addendum/supplement every year. This will enable us to protect those segments of the industry, which have acquired the necessary competence to manufacture drugs of quality in conformity with international standards. An autonomous organization with adequate infrastructure is a must for bringing out the Indian Pharmacopoeia on a regular basis. The existing bureaucratic procedures required to be followed by the I P Committee will not be able to do so even with the most noble intentions. The sooner the Ministry of Health and the Central Drugs Standards Control Organization hand over the activity to experts selected on merit only, and reduce, the ex-officio component to the barest minimum, the better it will be for updating the IP as efficiently as other well known pharmacopoeia.

As stipulation of the quality standards for the finished product alone was found inadequate to provide assurance of quality, the Rules included Good Manufacturing Practices (GMP) in Schedule-M. It deals with various important parameters including factory premises, working space and storage area, health, clothing of workers, medical services, sanitation

in the manufacturing areas, equipment, raw materials, master formula records, batch manufacturing records, manufacturing operations and controls, in-process controls, reprocessing and recovery, product containers and closures, labels and other printed material, distribution records, records of complaints and adverse reactions and the quality control system. Taken together, it provides for a system, which should give reasonable assurance of product quality if the principles are applied honestly. Most of the smaller units do not even understand their responsibilities under the GMP regime. The Drug Control administrative departments have failed to educate them in this regard, leading to the present state of affairs.

The Schedule-M for regulation of manufacture and quality control of Large Volume Parenterals (LVPs) has still not being revised, even though the NHRC had directed nearly two years ago that this be done expeditiously. There seem to be wheels within wheels that are impeding necessary action.

Except for a few manufacturers in the organized sector who have realized the importance of paying attention to Quality Management Systems (QMS), most of the manufacturers seem to be paying lip service to quality assurance. They don't seem to realize the importance of GMP and QMS. To be effective the QMS should have the visible and ongoing support of the top management. Most companies do not have a Quality Manual, with the result that the focus towards continuous improvement in manufacturing processes and reduction in failure costs is not there. Safety, health, and environment are not specifically addressed. Whatever little is being done is essentially an eyewash, and the regulatory authorities either do not have the infrastructure or are participants in the game of according tacit or active approvals to all and sundry. The mindset of the personnel involved in implementation of the provisions of the Act needs to be changed. They need training in this regard. Continuing education on a regular basis with documentary support is absolutely essential. The drugs inspectors and the laboratory personnel engaged in carrying out various tests must be exposed to experts with hands-on experience in the areas of their specific activity.

A large number of posts in the CDSCO continue to remain vacant for years for one reason or the other. It is difficult to imagine how all the four laboratories under the CDSCO are without regular directors for several years. The laboratory at Mumbai has only one officer on its rolls, namely the ad-hoc Director. The Central Indian Pharmacopoeia Laboratory, Ghaziabad created in 1966 for the specific purpose of preparing and validating standards for the Indian Pharmacopoeia, has been brought to the level of a routine drug-testing laboratory. Over the years, the entire Grade I and II officer posts falling vacant on

superannuation or for other reasons have been allowed to lapse. Only two ad hoc officers in CIPL including the Director are available to oversee its functioning. The CDTL, Chennai is without a regular head. The CDL, Calcutta, the senior most laboratory available with CDSCO, is no better. It has officers who are mostly promoted on an ad hoc basis. There are four officers in the pay scale of the Director. Thus, the CDSCO laboratories are like rudderless ships. If the state of affairs in the Central Government laboratories is like this, the position in the states is generally worse. Some states including Delhi have not cared to set up their own laboratories and are dependent on others. The less said about the so called approved private drug testing laboratories the better. Only a few of them come close to the required standards of Good Laboratory Practices (GLP), a term not very clear to even government laboratories, leave aside others.

It is essential to have a system of monitoring the performance of all drug-testing laboratories, whether from the Central or State governments or from the private sector, by independent experts of repute. Accreditation by the National Accreditation Board for Analytical Laboratories under the Ministry of Science and Technology must be made mandatory for all laboratories, to check this downward slide.

Under the Drugs & Cosmetics Act, the Central Government is entrusted with the responsibility of regulating the import of drugs and the approval of only new drugs. The licensing for manufacture, sale and distribution of drugs is the responsibility of states. It is not infrequent to find interpretation of the law by one state government diametrically opposite to that of another government. The differences are required to be sorted out by a statutory committee known as the Drugs Consultative Committee (DCC). Even after the DCC, presided over by the Drugs Controller General of India, takes a decision in certain matters, the state governments may not implement them fully or delay them inordinately because of political and other considerations.

To overcome some of the serious problems encountered in the implementation of the provisions of the Act, the concept of Central License Approving Authority was introduced in respect of certain notified categories of drugs, such as Blood and Blood Products, LVPs, Vaccines, etc. Thus personnel from the Central and State Drug Control administrative departments approve such units after joint inspections. It is imperative that the dual control over implementation of the provisions of the Act by central and state governments must come to an end sooner than later. There should be only one drug regulatory authority for the whole country. The pharmaceutical industry is presently under the control of the Ministry of Chemicals and Fertilizers for industrial regulation and pricing while the Ministry of Health & Family Welfare

regulates the quality and availability of drugs in the country. This arrangement too appears to be wasteful and overlapping There is need to bring it under unified control and the Ministry of Health appears to be the right choice for this task.

The growing complacency towards the inefficiency and corruption in the country has not spared the drug control departments. Stories in this regard are becoming more frequent and sensational than before. The problem needs to be handled with firmness by people who are upright. There is no dearth of them but the fear generated by the drug mafia seems to be preventing them from performing their duties without fear and favour. Necessary encouragement and protection must be provided to such persons.

PROGRESS IN RATIONAL USE OF DRUGS IN INDIA

N. K. Gurbani

The World Health Organization introduced the concept of essential drugs and rational use of drugs around 1973-75 in order to increase the accessibility of drugs to the majority of the population at affordable prices. However, due to lack of any positive initiation by the Central Government, and the state health authorities, there was no significant change for the next twenty years. In view of the diverse nature of India it's varied geography, population size and socio-cultural characteristics of twenty eight different states of India, each state has it's own health priorities and independent role in the management of health. The very first steps by the Central Government towards the implementation of compulsory generic nomenclature, to begin with five common drugs, could not succeed, due to legal hurdles initiated by affected multinational companies to protect their own brands.

The programme on rational use of drugs was initiated in the State of Delhi in the year 1994, when the then Health Minister of Delhi, Dr. Harsh Vardhan, found that in spite of the Government spending 30-35% of the health budget on drugs, these were not available to poor and needy patients. He termed the situation as "chaotic" on account of poor availability of required quality essential drugs, excessive availability of unnecessary drugs, traditional/herbal medicines and irrational combinations, lack of a common procurement list, irrational prescribing, polypharmacy and poor communication between patient and health professionals. To tide over this situation, a Drug Policy for the state of Delhi developed with the guidance of Prof. Ranjit Roy Chaudhury was adopted by the Delhi Government. This policy is based on the concept of Essential Drugs as proposed by the World Health Organization (WHO) and successfully implemented in several countries (like the UK, Norway, Australia, Bangladesh and Iran etc). The components of this new policy were –

(i) the development and implementation of an Essential Drugs List (EDL),

(ii) introduction of a improved system of pooled procurement,

(iii) quality control and assurance,

(iv) training and information on RUD,

(v) public awareness, and

(vi) research and monitoring.

The introduction of the drug policy and it's implementation in all aspects in time had shown rapid results on account of targeted focussed actions. The Table-1, below illustrates the vision envisaged, and achievement of objectives as set out in the Drug Policy Document in 1994:

Table-1

Steps/Vision envisaged in 1994	Action Initiation	Year of Achievement
1. Selection of an Essential Drugs List	1994	1994
2. Centralized pooled procurement system	1994	1995
3. Setting up a System of Quality Assurance, GMPs	1994	1995
4. Preparation of the State Drugs formulary	1994	1997
5. Training in RUD	1994	1994
6. Drug information	1995	1999
7. Preparation of STGs	1995	1998
8. Establishing ethical criteria for drug advertising and promotion	1995	1996
9. Conducting research and monitoring in drug use	1994	1995

By 1997, there was a dramatic change in the scenario regarding drug availability at all health facilities. Pooled procurement enabled the Delhi Government to obtain quality drugs at about 30% of rates being paid by other government agencies. Unwanted drugs and irrational combinations were phased out and shortages became rarer. The almost immediate success of this endeavour was christened the "Delhi Model" amongst development and health circles.

The almost immediate success of the 'Delhi Model' was mainly due to the coordinated team efforts of the collaborative triad formed by the Delhi Government, the health bureaucracy and the specialist assistance of the WHO. It also formed the basis for the intervention of the WHO on a sustained financial basis in an effort to spread the Essential Drugs Programme (EDP) to other states in India which emulate the results

obtained in Delhi. The WHO-India EDP was initiated in January 1998. Although, the Programme follows the guidelines of WHO-Geneva's EDM and Drug Action Programme (DAP), a distinctive feature of the India Programme is that it involves a direct collaboration of the WHO with an NGO, viz. Delhi Society for Promotion of Rational Use of Drugs (DSPRUD), which was formed in 1996 as a "triangle" of politicians, bureaucrats and technical experts dedicated to the cause of RUD. The DSPRUD is in charge of executing the Programme by means of direct involvement with the Central (federal) Government, various state governments and NGOs spread across the country. This network of collaboration has created within the Programme a powerful interface between the political leadership, the bureaucracy and a large number of health professionals and experts from related fields. Based on the basic goal of the EDP viz. to ensure availability and access to essential good quality medicines for all sections of society, whilst ensuring that these medicines are both prescribed and used rationally and keeping in view the "Delhi Model", the broad objective of the Programme as well as its major components are listed in Table-2.

Table-2

Objectives	Components
1. Improving the availability of safe and effective drugs	1. Development of a Drug Policy 2. Selection of an Essential Drugs list
2. Improving procurement, storage and distribution system for medicines	3. Establishment of a Pooled Procurement System
3. Establishing a Quality Control and Assurance System	4. Introduction of Quality Assurance System
4. Encourage rational prescribing and use of medicines	5. Encourage rational prescribing 6. HRD in the field of RUD
5. Strengthening/expanding health education programmes	7. Provision of objective Information to health professionals
6. Raising patient awareness	8. Provision of information about medicines to patients
7. Research and monitoring on all aspects of drug use	9. Research and monitoring of drug use

The Programme has expanded quite rapidly and significantly over the last three years. There has been a remarkable rise in the awareness of health professionals (doctors, nurses, pharmacists) as well as the

general public about the benefit of rational drug use through several training workshops and media exposure. Continuous advocacy and support to various state governments, core groups and committed persons by DSPRUD has resulted in the development of sound drug policies, essential drug lists, drug formularies, standard treatment guidelines and a large number of workshops on RUD in various states. Table-3 gives a summary of changes and activities that have been introduced in different States between the year 1997 before the launch of the Programme and the current situation in the year 2000. The comparisons are made on all essential elements/objectives of the Essential Drugs Programme.

In addition to the above, a number of national conferences viz. Association of Physicians of India (at Jaipur), Physiologists and Pharmacologists (at Bijapur), Indian Pharmacological Society (at Ahmedabad) and an International meeting on HIV/AIDS and Traditional Medicines at New Delhi had specific CME/sessions/focused on rational drug use. Inclusion of a one day RUD sensitization training module under a one month Induction Training Programme for newly recruited medical officers (to catch them young) at the State Institute of Health and Family Welfare (SIHFW) at Jaipur and a two week In-service Training Course at three regional health and family welfare centres (RHFWTC) at Jaipur, Ajmer and Jodhpur has allowed the percolation of RUD concepts down to the primary health care level centers. Over 500 Medical Officers belonging to different PHCs have been sensitized in this manner. The ripple effect of RUD advocacy and media exposure initiated under the Programme has motivated many individuals and NGOs to organize RUD activities on their own initiative without any financial support from the Programme. Important examples are implementation of RUD components viz. EDL, procurement, quality assurance, RUD training/workshops, STGs and antibiotic guidelines, patient education etc by the Christian Medical Hospital Association in Tamil Nadu; International Symposium on Prudent Use of Antibiotics at Jaipur; and workshops on Essential Drugs for district & medical college hospitals, drug utilization studies at PHCs and medical college hospitals at Mumbai, and teaching of RUD concepts in small interior areas of states, such as Athani, 70 km from Bijapur in Karnataka in collaboration with the local IMA branch.

However, despite this demonstrated success of the Government procurement system, the overall impact on the retail price of drugs in the open market is yet to be achieved. The price variability of drugs as available to Government supply and printed retail price of the same drugs in the open market is as high as ten times (Table-4). On account of lack of education and lack of consumer awareness on cost benefits of generic drugs, it is not the consumer (patient) who decides about which drug is to be purchased, but usually it is the prescriber who decides it. In view of the high powered promotional salesmanship by the pharmaceutical industry, such

Table-3

Components>	Essential Drug Lists			RUD Training to promote Rational Prescribing & RDU			Drug Policy			Quality Assurance			Pooled Procurement			Research & Monitoring			Patient Information			Drug Formalities (1) STGs (2) Journal/ Newsletter (3)		
Year (19–/20–)>	97	99	00	97	99	00	97	99	00	97	99	00	97	99	00	97	99	00	97	99	00	97	99	00
States																								
Delhi	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		1,2,3	1,2,3
Andhra Pradesh		✓	✓		✓	✓		✓	✓		✓	✓		✓	✓			✓						
Maharashtra		✓	✓		✓	✓					✓	✓			✓		✓	✓						
Himachal Pradesh		✓	✓		✓	✓		✓	✓		✓	✓			✓									1,2
Rajasthan		✓	✓		✓	✓	✓	✓	✓								✓	✓						
Punjab	✓	✓	✓			✓		✓	✓															
Best Bengal		✓	✓		✓	✓												✓						
Haryana		✓	✓																					
Chandigarh						✓												✓						
Karnataka					✓	✓															✓			3
Madhya Pradesh			✓			✓			✓															2
Assam & six NE States						✓																		
Tamil Nadu	✓	✓	✓	✓	✓	✓				✓	✓	✓										2	2	2

Table-4

Price/Cost Comparison Data of Selected Drugs with Delhi State Procurement System in Year 1999 of 1x10 Strip Packing

Sl. No.	Drug's Name, Dosage Form; Strength	Delhi Sate Procure-ment Cost* in Rs., Make	Generic Dealer Price after Distributor Margins & Printed M.R.P. in Rs.				Ethical Brand Product M.R.P. Range @	Price Ratio Delhi with Higher M.R.P. **
			Cadila Health-care	Cadila Labs	Cadila Labs	Paam Pharma		
1	Paracetamol Tab.; 500mg	**1.29** Nester	2.42 / 5.50	2.85 / 5.50	2.61 / 5.50	1.12/ 5.00	2.64 - **9.95**	**1:7.7**
2	Nimesulide Tab.;100mg	**3.70** Cadila	-	3.39 / 24.00	3.90 / 24.00	-	9.70 - **29.00**	**1:7.8**
3	Cotrimoxazole Tab.; DS	**5.85** Omega	-	8.65 / 14.59	9.15 / 13.42	5.05 / **20.00**	14.29 - 17.00	**1:3.4**
4	Doxycycline Cap.; 100mg	**5.85** Omega	11.16 / 14.51	-	9.55 / 31.20	-	15.80 - **62.00**	**1:10.6**
5	Tetracycline Cap.; 250mg	**4.80** Omega	8.33 / 14.70	9.58 / 15.22	8.35 / 14.70	4.83 / 13.44	10.52 - **15.72**	**1:3.3**
6	Ciprofloxacin Tab.; 500mg	**15.10** Auro-bindo	-	20.60 / 60.78	24.65 / 60.98	11.70 / **89.00**	45.00 - 88.00	**1:5.9**
7	Amoxycillin Cap.; 250mg	**7.90** Penam	11.95 / 32.00	12.55 / 35.00	-	7.00 / 35.00	15.71 - **37.50**	**1:4.7**
8	Ampicillin Cap.; 500mg	**13.30** Penam	19.66 / 58.00	25.25 / 56.00	-	12.20 / 65.00	48.10 - **77.28**	**1:5.8**
9	Cephelexin Cap.; 250mg	**13.20** Penam	24.87 / 61.00	26.90 / 62.00	26.30 / 61.00	-	32.50 - **64.50**	**1:4.9**
10	Norofloxacin Tab.; 400mg	**8.91** Micron	-	18.10 / 45.00	-	7.00 / **48.00**	20.50 - 45.00	**1:5.4**
11	Tinidazole Tab.; 300mg	**2.10** Lark	-	4.65 / 12.09	-	-	8.55 - **17.00**	**1:8.1**
12	Metronidazole Tab.; 400mg	**2.50** JB.Ph	-	-	-	2.70 / **10.00**	6.28 - 8-3.5	**1:4.0**

* Delhi State Procurement System ensures drug supply directly from original quality manufacturer only (c.f. GMP certification with necessary infrastructure and past track record, etc.) at lowest cost. For this purpose "Two envelopes selective tender system" (quality specifications & price bids) is followed. Price bids of only those manufactures are opened who have complied with the quality specifications.

@ Source: CIMS; This compassion is illustrative only. There could be a large number of manufacturers whose price range may vary as much or even more.

** The indicated ratio may exceed considerably in certain cases.

promotional measures need to be brought in line legally with the WHO criteria on ethical promotion of drugs. This, together with public education programmes on how to save effectively on drugs as well as some NGO or action group taking up this matter with the National Pharmaceutical Price Authority under the Ministry of Chemicals, towards rationalizing of retail prices will ensure the benefit of RUD activities to the people. The programme may like to take this up with key policy makers at the national level as an area of future action.

Since inception the WHO-India EDP has constantly strived to include into its fold more and more states to benefit as much of Indian population as possible. The Programme has already started spreading its wings to further reach out to the states of Uttar Pradesh (UP), Gujarat, Orissa, Kerala and the Indian Railways which have its own sizeable network of medical and health services viz. hospitals, dispensaries and health centres throughout the India. The Programme is reaching out further to private medical practitioners and specific areas of healthcare, such as Reproductive & Child Health (RCH), Cardiology and control of tuberculosis, etc. To ensure adequate patient information and education, special focus is also being made on training of pharmacists and dispensers to bridge the gap between the busy doctor and the patient. The Programme has also expanded to include practitioners employing traditional and herbal systems of medicine offering treatment to millions of patients living in the rural areas of the country, who have little access to modern medical facilities.

The impact of the WHO-India Essential Drugs Programme has been phenomenal. Apart from general increased awareness among doctors, nurses, pharmacists and the public due to constant programmes and media exposure, the Programme has very clearly demonstrated the benefits of rational use of drugs. Availability of essential drugs at all times has been ensured due to effective inventory control management facilities of a limited number of drugs. On account of the quality control and the pooled procurement system, the problem of spurious and substandard drugs has been almost eliminated. Based on the data available from Delhi and Tamil Nadu, there is a saving of about 35% by carrying out a transparent two-envelope bid system (technical for quality assurance and rates for price competitiveness) of pooled procurement of drugs. About 27% additional saving has resulted from rational prescribing and use of Standard Treatment Guidelines, while another 15% is saved by effective logistics of drug distribution. A further 10% waste is saved by increased compliance on account of enhanced communication between health professionals and patients.

EDUCATING MEDICAL STUDENTS AND MEDICAL PRACTITIONERS IN RATIONAL USE OF DRUGS

Uma Tekur

Irrational drug use has been a matter of great concern globally. Various studies conducted have stressed upon the importance of improving drug prescribing habits so as to ensure that the patient gets correct and safe medication, which has minimal side effects and is available at minimum cost, both to the patient and the community. Many reasons have been given for irrational prescribing by medical practitioners. Chief amongst them, is inadequate education in medical schools and lack of training of physicians in pharmaco-therapeutics and rational use of drugs. Rational drug use requires critical reasoning, clinical decision-making, integrating attitudes, skills and knowledge, problem solving capability, and patient communication skills.

To promote rational prescribing, various strategies like educational, managerial or regulatory interventions have been enumerated. In this paper, we will be discussing the educational strategies.

Interventions leading to an improvement in prescribing practices can be achieved through educating three groups of healthcare professionals:

1. Medical students
2. Teachers in medical schools
3. Medical practitioners in the public and private sectors

Traditional medical education concentrates essentially on imparting facts about drugs rather than teaching students problem solving techniques and hence, making a rational choice of drugs from the available treatment alternatives. A method which is commonly followed in the pre-clinical classes for teaching pharmacotherapy is through didactic lecture. In this, factual knowledge is presented. The students are then expected to apply this information to solve problems later during their clinical training.

It is imperative that teaching medical students in their formative years should closely simulate the clinical situation they will be exposed to

during their future clinical training. Towards this goal, in recent times, many medical schools in the West have adopted Problem Based Learning (PBL) as a method of teaching pharmaco-therapeutics. In this, clinical problems are presented to students right at the beginning of their pre-clinical course. In the process of solving simulated case studies, content knowledge is acquired. It has been stated that learning through PBL makes students more confident and helps them to take control of their own progress. An indicator of PBL's success has been its adoption in over nineteen disciplines around the world[1].

In recent times, didactic lectures are supplemented with various audiovisual aids like transparencies and slides. In a recent study conducted in Vellore, India[2], the usefulness of patient oriented problem solving (POPs) method of teaching pharmacology was compared with teaching the same using various audio-visual aids (AVA). The authors concluded that whereas teaching through AVA lectures influences both memory retention and analytical skills, POPs motivate self-learning. Hence, the educative values of these two systems of teaching is complementary. POPs, PBL and AVA lectures for teaching medical students are being employed in some other medical colleges in India[3].

The primary purpose of PBL during the pre-clinical setting is in teaching of basic sciences in a clinical context. The development of clinical reasoning skills has often been a complementary goal. Knowledge acquired by this method is stored, retrieved and used later during clinical practice. Students in the pre-clinical setting need to encounter a wide variety of problems which are relevant to their future clinical experience. However, the teacher-student ratio may be a limitation in the enforcement of the PBL method of teaching throughout the entire curriculum. One of the ways to overcome this is by incorporating PBL into the traditional form of teaching in undergraduate medical training.

It is a well recognised fact that the formal curriculam in medical and pharmacy schools are difficult to change. To overcome this, co-curricular activities have been suggested. Co-curricular programmes on essential drugs and rational prescribing have been conducted in many schools in India. Essentially, medical students who had completed their formal undergraduate medical education and started their compulsory internship training were included in these activities. These programmes were found to be very useful in sensitizing the interns on rational use of drugs during the formative years of their medical career[4].

The establishment of a resident doctor's education programme within teaching hospitals requires much attention. One of the chief problems

encountered during these programmes is lack of enthusiasm amongst the young medical graduates. It is essential, therefore, to modify some of the conditions which could enhance attendance levels.

Irrational prescribing is a habit which is difficult to cure but not impossible to prevent. The WHO Action Programme on Essential Drugs aims at improving pharmaco-therapy teaching for medical students. An international multi-center randomized study was conducted[5] to study the impact of a short problem-based training course in pharmaco-therapy using a WHO manual on the principles of rational prescribing. This course was field tested in seven countries. One of the centers was New Delhi, India. The study concluded that, for therapeutic problems discussed, both the retention and transfer effects were maintained for at least six months after the training session. In view of the difficulty of teaching medical students all the basic knowledge on the thousands of drugs available, this approach seems to be an efficient way of teaching rational prescribing. However, the method can be successful only when teachers are weaned away from the habit of transferring knowledge through lectures. This process should be accompanied by a change oriented towards problem based teaching of pharmacotherapy. The principles of rational prescribing should also be reinforced in the clinical phases of training in medical schools.

In order to effectively implement teaching of Rational Use of Drugs in the under graduate curriculum, it is important to train teachers in that area. A number of programmes have been conducted to sensitize and train the teachers in various aspects of Good prescribing, both in India and abroad.Pioneering work in this regard is being carried out in Groningen (The Netherlands) where an exhaustive workshop to include learning and teaching of problem based pharmaco-therapy to health professionals is conducted every year. This is an useful programme as it covers all aspects of learning, teaching, evaluation and implementation of a PBL module.

Numerous workshops have been conducted in Delhi, Rajasthan, Mumbai, under the aegis's of the WHO-Action Programme on Essential Drugs and the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD), during the course of which health professionals have been trained in various concepts of rational use of drugs including rational prescribing. These have proved to be successful as the participants have been highly appreciative of the various aspects of good prescribing that are included in these programme. However, in a recent study[6] conducted in Delhi, it has been observed that the impact of these training programmes is not sustained. Therefore it is

imperative that repeated sensitization is required to achieve any long lasting impact.

Training of physicians (both in public and private sector) as part of continuing Medical Education is important in ensuring rational prescribing practice. At present it has been observed that promotional activities of pharmaceutical companies form a major source of information to busy medical practitioners. This information is often biased, unscientific and tends to highlight the advantages while suppressing the limitations of the drugs. Complete information on comparative efficacy, side effects etc is also lacking. Workshops and seminars are important means of providing scientific and unbiased information.

In India, WHO-Delhi Society for Promotion of Rational Use of Drugs have been responsible in conducting numerous workshops to train medical practitioners in both the public and private sectors. These have proved to be very successful. While planning these workshops it is important that they are scheduled according to the conveniences of the participating doctors especially for the programmes for prescribers in the private sector. These should not interfere with their practice and hence, should be scheduled over a week end. The programmes should be specific, focussed and have very well defined objectives. Important topics that are seldom taught in medical schools but which are nevertheless important, should be incorporated. These include effective doctor-patient communication, medical ethics, importance of Adverse Drug Reaction Monitoring etc. Health workers at all levels need to know about rational use of drugs and how to apply this to community needs.

The prescribers in the public sector chiefly comprise the doctors working in Government owned health facilities. Hence, educational intervention should stress upon the development of Essential Drug Lists (EDL), and Standard Treatment Guidelines with reference to the EDL. As is well known, drugs available in the Government hospitals will chiefly comprise medicines from the EDL. However, while planning workshops for the prescribers in the private sector one should keep in mind the introduction of the latest drugs into the markets. For example, while discussing rational prescribing it is important and appropriate to talk about the methodology of choosing the right drug. This is important especially while comparing older drugs with newer drugs available in the market; for example, anti-microbial agents like amoxicillin and co-trimoxozole with newer ones like third generation cephalosporins or floroquinolones. It is important that the active participation of general practitioners is encouraged which will in turn stimulate them to improve the quality of prescription and thereby help in achieving more rational and effective use of medication.

Thomas et al[7] have observed that intervention to promote rational prescribing and rational use of drugs among practising physicians needs to be followed up by periodic reinforcement workshops. They also state that there is a desire among these prescribers to get unbiased information and the need to equip themselves with skills of critical evaluation of drug literature which are not part of a physician's training in the country.

There is a need to have a Human Resource Development department dedicated primarily to provide training to health professionals of various categories. This staff will need protected time for training purposes in order to implement and ensure effective programmes.

Irrational drug use has both a medical and an economic impact. Medically it leads to sub-optimal, ineffective or even dangerous therapy often leading to higher cost and economically to an enormous waste of resources. An effective drug policy and the economical use of public funds cannot be achieved solely by cost control.

Our experience has shown that isolated educational intervention on rational use of drugs does not have any far reaching impact. Learning is a continuous process and hence as part of Continuing Medical Educational progammes, there is a need to organize regular workshops and other interventional activities to promote rational use of drugs. These should be a part of ongoing training programmes and should be both extensive and intensive. Involvement of organizations like the local medical associations and medical councils should be sought to ensure greater acceptability of the programmes.

References

1. Kaufman DM. Problem Based Learning in pre-clinical context. Med Educ. 2000; **34**:512-518.

2. Kalpana Ernests, Anand KN, Kangasabapathy N, Chandy SJ, Kuruvilla Alice and Molly Thomas. Patient Oriented Problem Solving (POPS) approach and Audio Visual Aided (AVA) lectures in teaching pharmacology – A comparative study. Ind. J. Pharm. 1998; **30**: 97-101.

3. Salunkhe DS, Sewliker NG and Mandlecha RH. Patient Oriented Problem Solving (POPS) approach and Audio Visual Aided (AVA) lectures in teaching pharmacology. Not new for Pune University. Ind J.Pharm.1999; **31**: 39-40.

4. Bapna JS. Education in the concept of essential drugs and rationalised drug use. Clin Pharmac Ther. 1989; **45** (3): 217-21.

5. de Vries TPGM, Henning RH, Hogerzeil HV, Bapna JS, Bero L, Kafle KK, Mabadge AFB, Santoso B and Smith AJ. Impact of a short course in pharmacotherapy for undergraduate medical students: An International randomised control study. Lancet 1995; **346**: 1454-1457.

6. Uma Tekur : Monitoring the impact of a workshop on the rational use of drugs in a tertiary care hospital (unnpublished data).

7. Thomas M, Cherian AM, and Mathai D. Measuring the impact of focused workshops on rational use of drugs. Trop Doc.1997; **27**(4): 206-209.

RESEARCH IN RATIONAL USE OF DRUGS

Usha Gupta

A conference was convened by the World Health Organisation (WHO) at Nairobi in the year 1985, which was attended by a group of experts on rational use of drugs. Their definition of rational use of drugs was -

"The rational use of drugs (RUD), requires that patients receive medication appropriate to their clinical needs; the doses that meet their own individual requirements for an adequate period of time; and at the lowest cost to them and their community".

This conference marked the beginning of a global effort to promote rational use of drugs. In 1989, an overview of the subject concluded that very few interventions to promote RUD had been tested in the developing countries[1]. Since then the WHO Action Programme in Essential Drugs (WHO/DAP), the International Network for Rational Use of Drugs (INRUD) and other organisations have collaborated in an international effort in research to fill the knowledge gap[2, 3]. Several operation tools have been since developed to study the effects of different interventions on RUD through research programmes.

Many interrelated functions such as (a) the health system, (b) the prescriber, (c) the dispenser, (d) the patient, (e) the community are all involved in the therapeutic process and can contribute to irrational use in a variety of ways. Promoting rational use of drugs at any of these levels requires a well tested, proven and accepted intervention. The framework for such studies includes the following steps[4] :

Formative Studies - Wherein the problems with drug use are defined and quantified. The factors underlying such behaviour are identified.

Intervention Studies - All possible interventions (educational, managerial and regulatory) are considered and the appropriate one is chosen. Controlled randomised studies are conducted.

Follow Up Studies - Based on results obtained, cost effective interventions on a large scale are implemented.

Assessment Methods

ABC analysis - This method refers to categorisation of items by volume and value of consumption during a specific period of time. Class A items are mostly high volume and fast moving items. Such analysis helps in identifying high-cost examples of inefficient drug use, which can become a target for reducing procurement cost.

Prescribing and patient care surveys - are conducted by using WHO health facility core drug-use indicators[5]. These indicators are widely used and accepted as standard for identifying problems in drug use. These are quantitative indicators and give adequate information on irrationality existing at many levels of the therapeutic process. Indicator based studies can be followed by "in-depth studies" focussing either on specific disease or drug/group of drugs. These indicators are also used to study the impact of an intervention. To identify underlying factors for irrational behaviour, qualitative methods such as structured interventions and focus group discussions can be used.[6]

Drug use assessment in communities - refers to household surveys, survey at health centres by using structured and non structured interviews and focused group discussions. These are used as tools for identifying the problem and subsequent effect of an intervention on drug use behaviour in the community.[7]

Intervention Studies Reported in India - A Review

Intervention studies targeted at the health system are conducted to evaluate the effectiveness of an intervention to improve the accessibility of good quality essential drugs at an affordable cost. These are invariably regulatory and managerial interventions. Besides others, the result of two most important indicators i.e., availability of essential drugs in a health facility and the cost of treatment, reflect the effectiveness of an intervention. Data on such studies is not available in India. However, in Delhi State where such interventions have been introduced on a large scale it has been shown that there is a gradual increase in the availability of essential drugs in Delhi hospitals. The level of availability was 59.7% in one of the hospitals in the year 1995. In the year 2000, the level of availability has been shown to be 95.1%, thus indicating that the intervention had worked.[8]

Intervention studies targeted at prescribing behaviour. Most of the studies carried out in India were focussed on drug utilisation. To site a few examples, one of the studies reported from Pondicherry showed that in Government hospitals and the private sector, antimicrobial agents were prescribed in a large number (26%) of patients.[9] Similar studies focussing in speciality clinics, such as dermatology, have been reported[10,11]. In some studies the focus has also been on the number of drugs prescribed to a patient and on generic prescribing.[12] However, these are only formative surveys, identifying the existing problems in prescribing. None of these studies have introduced an intervention and measured the response. In Delhi hospitals, a study focussed on finding out the use of antibiotics in diarrhoea and acute respiratory infections (ARI) and it was found that use of antibiotics ranged from 74% to 89% in cases of diarrhoea and 42% to 67% in cases of ARI. Based on these results, educational interventions were introduced and a post intervention survey showed that a single educational intervention decreased the use of antibiotics in ARI in the study group (from 66% to 51%) as compared to the control group (from 61% to 60%). However, in case of diarrhoea the results were the same in the control as well as the study groups. The use of antibiotics decreased from 80% to 61% in the control group and 78% to 64% in the study group.[13]

Intervention targeted at the dispenser. The quality of dispensing influences the rational use of drugs by patients. Indicators such as patient's knowledge of drug use, time spent by the dispenser while dispensing the drugs and labelling of medicines give adequate information about the dispensing practices. Again data on intervention based studies is sparse. In most of the drug utilisation studies these indicators have not been studied. There are isolated reports on patient's knowledge about drug use studies. In one of these studies, knowledge was found to be extremely low (34%). An attempt was made to conduct an intervention based study in Delhi hospitals. Base line survey findings revealed that only 37% patients had knowledge about drug use. A randomised controlled study was planned and conducted. An intervention which included verbal and written information (Patient's Information Leaflets) to the patient about drug use was introduced. The results showed that there was a two to three fold increase in all the indicators in the study group as compared to the control group.[14]

Intervention targeted at the patient and the community. Besides prescribers and dispensers, patients' individual factors and cultural beliefs also influence drug use. Studies have not been conducted even to find out the extent of the existing problem about drug use in communities.

Summary

From the available data, it appears that research on rational use of drugs in India is still in it's infancy. There is a need to conduct controlled intervention studies to document the acceptable, suitable and economical interventions, which could later on be implemented on a larger scale.

References

1. Laing RO, Rational Drug Use: an unsolved problem. Tropical Doctor 1990:20, 101-3.

2. Laing RO, Intrnational Network for Rational Use of Drugs (INRUD), Tropical Doctor 1990:20, 201-3.

3. Quick JD, Laing RO, Ross Degnan DG. Intervention research to promote clinically effective and economically efficient use of pharmaceuticals: The International Network for Rational Use of Drugs. Journal of Clinical Epidemiology; 1991:44 (suppl 2): 57S-65S.

3. Quick JD, Rankin JR, Laing RO, et al.(eds). Managing drug supply, management science for health in collaboration with World Health Organization. West Hortford, CT: Kumarian Press, 1997.

5. WHO. How to investigate drug use in health facilities (selected drug use indicators). WHO/DAP/93-1 Geneva: World Health Organization, 1993.

6. Archinful DK, Das AM, Hadiyono JP et. al. How to use qualitative methods to design interventions. Washington DC: INRUD. December 1996.

7. WHO. How to investigate drug use in communities. WHO/DAP/ 92.3. Geneva. World Health Organization, 1992.

8. Chaudhury RR. Rational use of drugs: Delhi's change in policy changes lives, Essential Drugs Monitor. 1999: 27:2

9. Shewade DG, Pradhan SC. Auditing of prescription in government teaching hospital and four retail medical stores in Apondicherry, Indian Journal of Pharmacology, 1998:30;408-410.

10. Minocha KB, Bajaj S, Gupta K, Gupta M. A clinical pharmacological study of out-patient prescribing pattern of dermatological drugs in an Indian tertiary hospital 2000: 32:384-385.

11. Roy V, Rewari S, Reddy BSN, Bapna JS. Prescribing topical corticosteroid in dermatology out-patient in tertiary care hospital: 1998: 30:344-345.

12. Shoba JC, Naidu MUR, Venkatesh K, Rameshkumar T, Usha Rani P, Vijayakumar T. Pharmacy based prescription event monitoring in a tertiary hospital: 1999: 31:377-378.

13. Sharma S, Gupta U, Chaudhury RR, Bapna JS: Impact of an educational intervention on prescribing behaviour of physician with a focus on antibiotics use in ARI and acute diarrhoea at primary health centres in Delhi (submitted for publication).

14. Gupta U, Sharma S, Chaudhury RR. Impact of drug information on patient's knowledge about Drug use in Delhi hospital (personal communication).

RATIONAL DRUG USE & ECONOMIC GAINS : THE DELHI EXPERIENCE

J. S. Bapna

Economic pressures have made it increasingly difficult for the government to provide adequate funds for the supply of drugs to health facilities. There is a growing dependence on private sector pharmacies and drug outlets, but prices are often beyond the reach of much of the population in need of drugs. Financing of drugs is a critical issue for several reasons. Firstly, because drugs save lives and improve health. It is important that drug financing must ensure access to essential drugs for all segments of the population. Secondly, drugs are costly, and most ministries of health incur the biggest expenditure on the purchase of drugs. Thirdly, inadequate funding for drugs means that expenditure for staff salaries and other health care costs may be used inefficiently or simply wasted. There is always a demand for increasing the government's budget for health. Since budgets are never large enough, health managers must constantly decide which of the several courses of action to follow. Often reallocation of the budget is the soft option but not necessarily a correct one. Insufficient attention has perhaps been paid to improving the use of existing resources and to reducing waste in the drug supply system.

This chapter contains two main sections. The first section is a background situation before the introduction of the drug policy in Delhi State and the second section is a description of experience gained from ongoing essential drugs programmes, indicating how much can be saved through measures to rationalize drug use.

Delhi State took the lead in developing a comprehensive drug policy in 1994. This was through the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD), which worked with the State Government with support from the World Health Organization. Prior to this, the situation regarding availability of drugs in the public sector health facilities, was dismal. Each health facility had its own list of drugs with its own system of procurement. Only a few essential drugs were available and the non-essential drugs accumulated in the stores. The doctors were under pressure to prescribe drugs even when these were not needed, to avoid expiry of drugs. Several drugs reached their expiry date causing wastage of money, even when resources were meagre. Herbal

drugs were procured in large quantities (at one facility one third of drugs procured were herbal drugs) about which doctors did not have any knowledge of its actions and indications. All they had to do was to prescribe these in order to get rid of the stocks. In one of the large facilities, as many as 120 of the 300 drugs in the list were of the kind that would not have much use. On reviewing the list by the heads of the departments it was found that about half of these were not at all required and could be deleted from the list. However, the staff from the purchase section who had little knowledge about the drugs continued to procure these for reasons best known to them. Drugs, which could not be procured by the tender system, were directly purchased from the Government super market at a very high price. Thus the meagre resources were wasted on drugs that were not needed causing a short supply of essential drugs.

Soon after Delhi was declared a state, a state government was formed. The Health Minister took the initiative to invite the experts from the government and non-government sectors in the field and a drug policy based on sound principles of the essential drugs concept was developed. The political will in developing the policy was the cornerstone of it's success. Knowing that the Government cannot develop and implement the drug policy alone, a registered non-governmental organization, the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) was formed. The unique thing about it was that its members chaired various government committees that worked towards the development of drug policy.

A team of dedicated persons began work on different aspects of the policy. The Health Minister declared a policy statement approved by the cabinet. Soon a gazette notified an Essential Drugs Selection Committee consisting of sixteen members. The committee comprises academicians, drug control administrators at the centre and state, bureaucrats, eminent private practitioners, hospital administrators was formed with Professor Ranjit Roy Chaudhury as advisor of the Committee.

The starting point for an essential drugs policy is the careful selection and quantification of drug needs according to the health needs of the population to be treated. The savings to be made from a careful selection of drug needs generally range from 10-60% or even more in a few cases. Careful selection is a crucial first step in improving drug supply management. The selection involves balancing considerations of cost with those of efficacy, safety, ease of administration, and other local variables. Therefore, one of the initial steps was for a high level committee to draw up a common list of two hundred and fifty essential drugs and another list specifically for smaller hospitals, containing one hundred drugs. The first essential drugs list was drawn up in 1994 based on WHO guidelines and included 329 drugs in twenty-eight

different categories. Both lists were revised in 1996 and again in 1998, when eighteen new drugs were added and twelve were deleted.

After the selection of drugs, the next crucial issue is the quantity of each drug that will be needed over a period of time, which is usually a year. Procurement is the area of drug supply in which great improvements in savings can be made. A common pool for procuring drugs was introduced, supervised by a Special Purchase Committee. Soon all hospitals run by the Delhi Government began to use the same medicines. Now a much improved "double envelope" system of obtaining technical bids and price bids in two separate envelopes ensures that only serious players who fulfill the technical criteria are considered. Two or three suppliers with a minimum turnover of twelve crores are selected for each drug. Doctors are requested to prescribe only those drugs, which are on the procurement list. However, hospitals are given some flexibility as they can prescribe non-listed drugs upto the value of 10% of their budget.

The new measures resulted in a sharp fall in the procurement prices of essential drugs (Table 1) with bulk buying, reducing costs. Thus, bulk purchasing of carefully selected essential drugs was estimated to save nearly 30% of the annual drug bill for the Government of Delhi. Pooled procurement is now in place for all state run hospitals and one hundred fifty primary health centres. The programme also ensures the quality of drugs supplied to Delhi hospitals and centres. This has led to reducing duplication of work, better prices (30-40% lesser cost), quality assurance and GMP inspections.

Besides savings on pooled procurement prices, much of the savings were made by avoiding emergency local purchases and by preventing expiry of drugs by bulk purchases and procuring only those drugs which are more frequently required. The availability of essential drugs also improved both for outpatients and inpatients in Delhi hospitals.

Drugs are wasted during storage and distribution in mainly three ways: deterioration due to poor storage conditions, expiry of drugs due to improper estimates or poor inventory control and management and loss due to pilferage, theft or loss during distribution to lower level facilities. Looking ahead, the government has approved the setting up of a state Drug Authority at Karkardooma, which will be responsible for drug procurement, storage and distribution. The premises are already under construction and will incorporate modern computerized storage and inventory control techniques. Thus, significant savings (as much as 10-25%) can be made by improving storage conditions and protecting drugs from heat and moisture, improving inventory control to reduce possibility of drugs expiring.

Improving prescription practices can be conductive to major savings. Courses in rational prescribing have been organized successfully with the help of local and international partners. Training in rational use of drugs is focussed on how to identify and solve problems related to the prescription, dispensing and consumption of drugs. More training services for doctors, pharmacists and nurses are being held in Delhi.

Prescribers have strong opinions about drugs, which are influenced by their medical training and colleagues, patient expectations, and, also the efforts of the pharmaceutical industry to encourage them to prescribe newer, and more expensive drugs. Over prescribing, and inappropriate prescribing, including excessive use of injectables and antibiotics can result in a great deal of wastage of drug supplies. Efforts to involve prescribers in developing and using standard treatment schedules can be effective in reducing over prescription and can save as much as 50-70% of expenditure on drugs. To strengthen prescribing, the guidelines for treatment at primary health care facilities were prepared to help doctors working in this sector. The guidelines included treatment for fifteen priority diseases commonly encountered by physicians and five diseases commonly encountered in children. Comprehensive guidelines for most priority diseases to help doctors at all levels of health care are in the process of being prepared.

Reducing over prescription is an important step towards potential savings. Results of the survey in Delhi primary health centres and colony hospitals (20 bedded hospital) showed irrational use of antibiotics. Antibiotics were prescribed to nearly 80% of all patients suffering from diarrhoea and in 60% of the acute respiratory infection episodes; both the conditions are presumably of viral origin. About 5-10% prescriptions were found to have the same antibiotic under different brand names[1].

When actual prescriptions from a number of health centres were compared with "best practice i.e. standard treatment guidelines" prescriptions for ARI and diarrhoea as established by the National ARI and Diarrhoea Control Programme, the cost of drugs could have been reduced by 50% and 63% in ARI and diarrhoea respectively[2]. Alternatively, approximately two three times as many patients could have been treated within the same budget. Further, when cost of therapy at prices obtained by pooled procurement system and the retail sector (minimum prices) was compared for ARI and diarrhoea, it was observed that the cost of therapy at prices obtained by pooled procurement system is half of the treatment cost in the retail sector[2]. All these have serious repercussions on the status of increasing antimicrobial resistance in the country as well as effectiveness and cost of therapy. The prescriber's knowledge about the use of antibiotics

and risks was generally sufficient, yet they overused antibiotics. The motivating factors for inappropriate prescribing identified in these studies are complex though more or less typical and comparable to reports from other countries[3-4]. Deeply rooted factors associated with the physician's prescribing behaviour, concepts about aetiology, perceptions about oral rehydration therapy and parental expectations can perhaps be targeted through regular discussions with prescribers about these issues.

Finally we come to the last link in the chain of events involved in drug supply- the patient himself. When the patient finally gets the drugs does he take them as intended by the prescriber? Overwhelming evidence from industrialized countries show that compliance is, on average about 50% - only half of the patients take the drugs as they should. It is likely that as much as 25 % patients fail to take prescribed drugs as anticipated, resulting in a significant waste. There is a reason to expect that the situation is worse in the developing countries, given the lack of instructions provided with prescription, low literacy, and poor dispensing practices[5]. An average consulting time and dispensing time is 1.5 minutes and 50 seconds respectively in health facilities and 50% of the patients had the knowledge of important dosage instructions[6]. This is especially common for drugs to treat infections as well as other chronic ailments like diabetes and cardiovascular diseases. Efforts to improve dispensing practices and to provide information to patients regarding dosage, mode and frequency of administration, duration and so on were initiated in two of the Delhi hospitals by providing instructions to the patients at the pharmacy exit and written drug information in the form of leaflets[7]. The results are very encouraging and efforts are being made to build a bridge of trust between the prescriber and the patient, to explain the use and administration of drugs, and to improve patient information and dispensing practices on a wider scale at the level of community and health care facilities. These efforts can be useful in improving patient compliance and better treatment outcome and thus potential savings in drug supply.

Before implementation of the drug policy in Delhi, each hospital had its own list, medicines were procured under many different brand names, supply was erratic and prescribing, very often, unrestrained. Although 30-35% of the hospitals' budget was spent on medicines, their shortage was chronic. However, within four years of the new drug policy being introduced through the rational drug use programme, there has been a dramatic change. Ninety percent of the budget is spent on essential drugs, the quality of drugs is generally assured and prescribing is more rational. Most importantly safe and effective drugs are now available.

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for patients. There are possibilities for significant savings in most areas of the present drug supply management and use. Potential savings from individual rationalization measures (summarized in Table 3) range from 10-60% or more[5]. The biggest gains appear to have come from the adoption of better procurement and prescribing practices. Each sub-optimal decision made during the drug supply and management process involves a cost because drugs flow through a system and poor decision successively reduces the value of the drugs remaining in the system. Thus, rationalization measures can help to lower costs, which in turn result in prices that are affordable for a larger proportion of the population.

References

1. Sharma Sangeeta, Gupta U, Roy Chaudhury R, Bapna JS. Impact of an educational intervention on prescribing behaviour of physicians with a focus on antibiotic use in ARI and diarrhoea at primary health centres in Delhi. J Health Management (under publication).

2. Raj K.Gulati, Sharma S. Gupta U, Bapna JS and Roy Chaudhury R. Effect of rational prescribing on cost of therapy in acute respiratory infection and diarrhoea. Data on file (Project No. 006/2000), Delhi society for Promotion of Rational Drug Use, Delhi.

3. Santoso B, Suryawati S, Prawitasari JE. Small group intervention vs formal seminar for improving appropriate drug use. Soc. Sci. Med. 1996, 42:1163-1168.

4. Schwartz RK, Soumerai SB, Avarn J. Physicians' motivations for non scientific drug prescribing Soc Sci Med 1989;28:577.

5. WHO/DAP/88.10 Financing essential drugs: Report of a WHO workshop. Action Programme on Essential Drugs and Vaccines. World Health Organization Geneva.

6. Gupta U, Sharma S, Bapna JS, Roy Chaudhury R. To investigate the extent of antibiotic use in acute respiratory infection (ARI) at primary health centres in Delhi. Data on file (Project No. 001/ 2000), Delhi society for Promotion of Rational Drug Use, Delhi.

7. Roy Chaudhury R, Jha Jeevan, Gupta U, Sharma S. Impact of drug information on patient's knowledge about drug use at Deen Dayal Upadhayay hospital. Data on file (project No. 002/2000) Delhi society for Promotion of Rational Drug Use, Delhi.

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Table-1

Comparative prices (in rupees) at which drugs were procured in 1995.

Drugs	National drug procurement agency	Delhi state by pooled procurement and selective tender
Amoxicillin injection	11.4	7.5
Cloxacillin injection	13.5	4.7
Erythromycin tablet 250 mg	5.7	1.5
Erythromycin syrup	20.8	9.8
Amikacin syrup 500 mg	92.8	23.6

Table-2

Cost of therapy, acute respiratory infection (ARI) and diarrhoea compared to standard treatment guidelines (STGs) according to prices obtained by pooled procurement system before and following educational intervention in the form of prescription audit feedback and small group interactive workshops

Group	Cost of therapy (Rs.)					
	ARI (Mean ± SE)			Diarrhoea (Mean ± SE)		
	Pre-Inter-vention	Post-Inter-vention	As per STGs	Pre-inter-vention	Post-Inter-vention	As per STGs
Control	9.56±1.21	10.19±1.27	4.75	17.82±1.85	15.97±1.6	11.20
Intervention	9.31±0.81	8.29±1.15		13.88±0.76	14.42±0.53	

Table-3

Estimates of potential savings from rational drug use.

		Average	Highest
1.	Selection using cost-effectiveness criteria	10%	60%
2.	Quantification of drug needs as basis for ordering	15%	30%
3.	Procurement using competitive bidding procedures Storage and distribution:		
	a) proper storage conditions	25%	30%
	b) good inventory management and low expiration	15%	20%
	c) reduction of theft and pilferage	20%	60%
4.	Rational prescription	50%	70%
5.	Improved patient compliance	20%	25%

RECOMMENDATIONS FOR THE FUTURE

Ranjit Roy Chaudhury

Many suggestions for improving the medicines scenario in the country have been made in the foregoing pages by experts who are experienced and knowledgeable. The background and the present prevailing situation have been adequately described with - the strengths and weaknesses of the present system, the complexities and the paradoxes, and the successes and failures. There is no need to refer to these again. In this section, a few recommendations, which need immediate attention, will be highlighted. If these are tackled and if a strategy is developed around these, this could become a national programme of action which, if implemented could not but lead to a remarkable improvement in the regulation, production, quality, accessability and use of medicines in India.

Reform of drug regulation

It is imperative to frame a new Drugs Act which would ensure safety, efficacy and quality of drugs in use and also enhance the rational use of medicines. The situation prevailing today, when around 50,000 drug formulations have been licensed, and where substandard and counterfeit drugs find the way into the market, cannot be allowed to continue. Some of the features of the new Drugs Act would be:

1. No registration of any new formulation would be allowed unless it is approved both by the state licensing body and the central drug regulatory authority. This has to be rigidly enforced.

2. Recommendations of the Drugs Consultative Committee should be made mandatory.

3. Regulation of medical devices should be brought under the purview of the Drugs Act.

4. E-commerce of drugs should be regulated under the Drugs Act.

5. The office of the Drugs Controller General should become a National Drug Authority with its own laboratories in New Delhi, its own experts and a large number of expert committees and panels. The staff have to be intensively trained and greatly expanded to meet demands.

6. The chain of Drug Quality Control laboratories at the Centre and in the States need to be greatly strengthened and given autonomy and authority to carry out its designated functions.

7. The method for assessing, reviewing and clearing new drugs should become uniform, transparent and rapid so that the Indian pharmaceutical houses could get their new drugs assessed and cleared at the earliest to meet global competition.

Strengthening of quality assurance systems

In addition to the strengthening of the drug regulatory system at the centre and in the states and establishing a network of quality control laboratories, the following initiatives would go a long way in ensuring the quality of drugs.

8. Good Manufacturing Practices (GMP) should become mandatory for pharmaceutical houses and GMP inspections should be carried out on a regular basis. This should be done on a coordinated basis so that the report of inspection obtained by one state could be used by the other states. This needs the establishment of a GMP Inspection Organization, which could be either in the government sector or preferably be an autonomous body. This Organization would bring out every year a list of pharmaceutical factories which had been inspected in the past year and where the GMP have been found to be satisfactory.

9. Similar inspection followed by analysis of coded samples within the framework of an external quality control system should be made of laboratories carrying out analysis of drug samples. Laboratories in the government set-up and private laboratories should be included in this study. An accrediting body should issue the list of laboratories where the facilities and testing were found to be up to the mark every year.

10. The Indian Pharmacopoeia should be brought out every year. An autonomous organization with adequate infrastructure should be established for carrying out this much needed and very important function.

11. Results of post marketing studies should mandatorily be made available to the office of the Drugs Controller General.

Procurement, storage and distribution of drugs

12. The transparent two envelope system of procurement of drugs which has proved so successful in Delhi State and Tamil Nadu should be introduced in the states and in the Central Government including the Medical Stores Organization of the Government of India. This system reduces the cost at which medicines are obtained, increases the accessability to the medicines and enhances the quality of drugs being obtained.

13. There should be no purchase preference for state owned enterprises, public sector units or for small scale industries as these preferences are uneconomical and unacceptable from the point of view of quality of drugs. Where the health of an ill person is involved, there can be no justification of not ensuring, to the maximal degree possible, that the medicines being administered are of the standard quality. No compromise can be acceptable.

14. The distribution of medicines to the farthest corners of the country should be entrusted, in pilot projects in some districts to the private sector. It is not satisfactory to rely only on governmental distribution systems, which has proved to be ineffective. If this involvement of the private sector improves the distribution then they could also perhaps be entrusted with procurement and distribution.

Infrastructure for drug discovery and development

The following steps need to be taken if drug development and clinical evaluation of new drugs is to proceed in a manner to make India a global player in new drug discovery and use. Fortunately, the Indian Council of Medical Research has made an excellent beginning by establishing its network of Advanced Centres in Clinical Pharmacology, Toxicology and Traditional Medicine throughout the country. The ICMR network for clinical evaluation of traditional remedies and medicinal plants is unique. However, other national and state efforts need to be made in the following directions:

15. Development of centres for carrying out preclinical toxicology studies of compounds and plant products before clinical evaluation. These should be available to any researcher or group of scientists who have interesting compounds but today cannot get these toxicologically evaluated easily.

16. Training of scientists for carrying out preclinical toxicological studies is very necessary.

17. Development of centres of clinical pharmacology is essential if the country is to participate in the drug discovery scenario that is expected in India. These should include not only centres for carrying out Phase II and III Clinical Trials but also for undertaking pharmacokinetic and bioavailability studies of both synthetic compounds and plant products.

18. Training of clinical pharmacologists is important if the new drugs being developed are to be evaluated scientifically. Researchers in the traditional systems of medicine should also be trained in clinical pharmacological and clinical trial methodology as clinical evaluation of products of these systems of medicine should also be carried out scientifically at institutes and colleges of these systems.

Cultivation of medicinal plants

19. Incentives need to be provided to farmers to prevent medicinal plants becoming endangered and getting lost. These incentives could be in the form of funds for agrotechnology, soft loans to farmers for taking up cultivation of medicinal plants and investments for Green House Development.

Rational use of drugs

20. Programmes in rational use of drugs should be introduced and further strengthened in a comprehensive manner by every state government and the national government. The Delhi Society for the Promotion of Rational Use of Drugs has clearly demonstrated that such programmes can be introduced and implemented and lead to better use of medicines. It is now opportune for the government and non-governmental organizations to build on what has been achieved to make the programme an effective national programme. This programme should encompass also the corporate sector and the general practitioners in addition to the government doctors and government hospitals.

Human resource development

21. Training has been mentioned earlier in relation to toxicologists and clinical pharmacologists. However, human resource development programmes need to be developed and implemented in a continuing manner for all categories of persons involved in the medicines scenario.

Research

22. Research needs to be carried out, again, in all aspects of drug use. A continuing monitoring system for cost of drugs, accessability, quality and use should be strengthened in every state. Research is urgently needed on the economics and behavioural aspects of drug use.

Infrastructure charge

23. Serious thought should be given to bringing into the Ministry of Health and Family Welfare the responsibility also for production and pricing of drugs. The artificial division created for implementing the Hathi Commission Report by two different departments, the Ministry of Chemicals and Fertilizers and the Ministry of Health and Family Welfare has led to many problems. A single ministry should look after both the economic and the "human face" aspects of the production and use of medicines.

Conclusions

About 30% - 35% of the health budget at the centre and in the states is spent on medicines. The papers in this publication show clearly that this large proportion of the budget could be more effectively used. The number of people who have access to allopathic medicines in the rural areas is only around 35%. What is needed is not necessarily more resources but better management of the existing resources. Many more persons requiring medicines could be provided good quality medicines with the same resources if changes are made.

The importance of programmes of rational use of drugs cannot be underestimated. However, this has largely not been understood nor appreciated. There does not appear to be a sense of urgency in developing and implementing such programmes in rational use of medicines.

It is hoped that this publication will help our policy makers and others to understand better what needs to be carried out in this important area.

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